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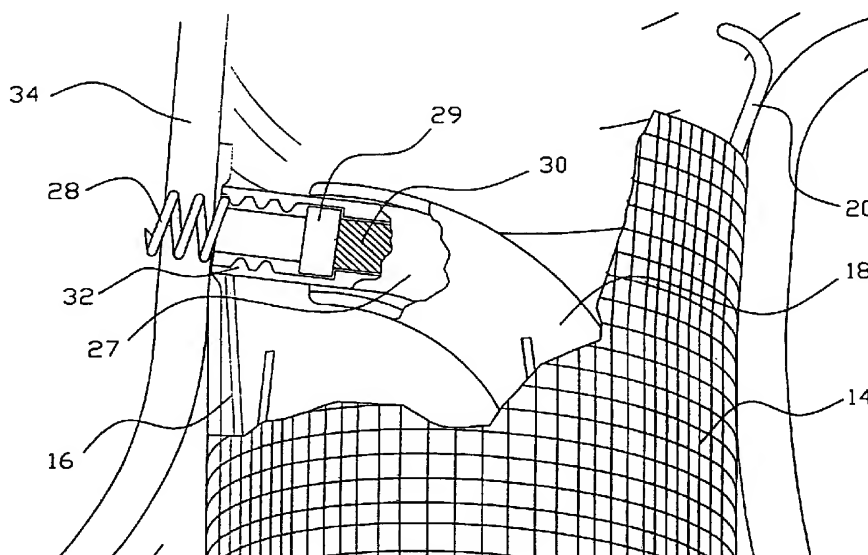
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

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(54) Title: **ENDOVASCULAR ANEURYSM REPAIR SYSTEM**



(57) Abstract: Method and apparatus for implanting radially expandable prostheses (14) in the body lumens rely on tacking or anchoring of the prostheses with separately introduced fasteners (28). The prostheses may be self-expanding or balloon expandable. After initial placement, a fastener applier system (27) is introduced within the expanded prostheses to deploy a plurality of fasteners at at least one prosthesis end, usually as each end of the prosthesis. The fasteners are usually helical fasteners which are delivered from a helical track in the fastener applier by rotation with a rotator wire. The fasteners will be applied singly, typically in circumferentially spaced-apart patterns about the interior of each end of the prosthesis.



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ENDOVASCULAR ANEURYSM REPAIR SYSTEM**Related Application**

This application claims the benefit of co-
pending United States provisional application Serial No.
5 60/333,937 filed 28 November 2001.

Background of the Invention

The invention relates generally to the
attachment of a vascular prosthesis to a native vessel,
and in particular, to a method and system of devices for
10 the repair of diseased and/or damaged sections of a
vessel.

Description of Related Art. The weakening of a
vessel wall from damaged or diseased can lead to vessel
dilatation and the formation of an aneurysm. Left
15 untreated, an aneurysm can grow in size and will
eventually rupture.

For example, aneurysms of the aorta primarily
occur in abdominal region, usually in the infrarenal area
between the renal arteries and the aortic bifurcation.
20 Aneurysms can also occur in the thoracic region between
the aortic arch and renal arteries. The rupture of an
aortic aneurysm results in massive hemorrhaging and has a
high rate of mortality.

Open surgical replacement of a diseased or
25 damaged section of vessel can eliminate the risk of

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vessel rupture. In this procedure, the diseased or damaged section of vessel is removed and a prosthetic graft, made either in a straight or bifurcated configuration, is installed and then permanently attached and sealed to the ends of the native vessel by suture. The prosthetic grafts for these procedures are usually unsupported woven tubes and are typically made from polyester, ePTFE or other suitable materials. The grafts are longitudinally unsupported so they can accommodate changes in the morphology of the aneurysm and native vessel. However, these procedures require a large surgical incision and have a high rate of morbidity and mortality. In addition, many patients are unsuitable for this type of major surgery due to other co morbidities.

Endovascular aneurysm repair has been introduced to overcome the problems associated with open surgical repair. The aneurysm is bridged with a vascular prosthesis, which is placed intraluminally. Typically these prosthetic grafts for aortic aneurysms are delivered collapsed on a catheter through the femoral artery. These grafts are usually designed with a fabric material attached to a metallic scaffolding (stent) structure, which expands or is expanded to contact the internal diameter of the vessel. Unlike open surgical aneurysm repair, intraluminally deployed grafts are not sutured to the native vessel, but rely on either barbs extending from the stent, which penetrate into the native vessel during deployment, or the radial expansion force of the stent itself is utilized to hold the graft in position. These graft attachment means do not provide the same level of attachment when compared to suture and can damage the native vessel upon deployment.

Accordingly, there is a need for an endovascular aneurysm repair system that first provides a prosthetic graft, which can adapt to changes in aneurysm

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morphology and be deployed without damaging the native vessel and second, a separate endovascular fastening system that provides permanent graft attachment to the vessel wall.

5 Summary of the Invention

The methods and apparatus for implanting radially expandable prostheses in the body lumens are described. In particular, the present invention provides improved methods and systems for implanting vascular
10 stents and stent-grafts into blood vessels, including both arterial and venous systems. In the exemplary embodiments, stent-grafts are placed in vasculature to reinforce aneurysms, particularly abdominal aortic aneurysms.

15 In the first aspect of the present invention, a radially expandable prosthesis is placed in a body lumen by first expanding at least one scaffold of the prosthesis at or near an implantation site within the body lumen, e.g., at or from vasculature on one side of
20 an aneurysm. After expanding the scaffold of the prosthesis, a plurality of fasteners are introduced through the prosthesis in the region in the scaffold to anchor the scaffold in place. The scaffold may be elastic, typically comprised of a shape memory alloy
25 elastic stainless steel, or the like. For elastic scaffolds, expanding typically comprises releasing the scaffolding from constraint to permit the scaffold to self-expand at the implantation site. The constraint may be radial constraint, i.e., placement of a tubular
30 catheter, delivery sheath, or the like over the scaffold in order to maintain the scaffold in a radially reduced configuration. Expansion is then achieved by pulling back on the catheter sheath to permit the scaffold to return to its larger diameter configuration.
35 Alternatively, the scaffold may be constrained in an

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axially elongated configuration, e.g., by attaching either end of the scaffold to an internal tube, rod, catheter or the like, to maintain the scaffold in the elongated, reduced diameter configuration. The scaffold
5 may then be released from such axial constraint in order to permit self-expansion.

Alternatively, the scaffold may be formed from a malleable material, such as malleable stainless steel of other metals. Expansion may then comprise applying a
10 radially expansive force within the scaffold to cause expansion, e.g., inflating a scaffold delivery catheter within the side of the scaffolding order to affect the expansion.

The vascular prosthesis may have a wide
15 variety of conventional configurations. In the preferred placement of the vascular stent-graft, prosthesis would typically comprise a fabric other blood semi-impermeable flexible barrier which is supported by a scaffold, typically in the form of a stent. A stent can have any
20 conventional stent configurations, such as zigzag, serpentine, expanding diamond, or combinations thereof. The stent structure may extend the entire length of the graft, and in some instances will be longer than the fabric components of the graft. Alternatively, the stent
25 will cover only a small portion of the prosthesis, e.g., being present on at 1,2, or 3 ends. The stent may have three or more ends when it is configured to treat bifurcated vascular regions, such as the treatment of abdominal aortic aneurysms when the stent graft extends
30 into the iliac arteries. In certain instances, the stents may be spaced apart along the entire length, or at least a major portion of the entire length, of the stent-graft, where individual stent structures are not connected to each other directly, but rather connected to the fabric
35 or other flexible component of the graft.

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Introduction of the fasteners will typically be effected after the prosthesis has been initially placed. That is initial placement will be achieved by self-expansion or balloon expansion, after which the prosthesis is secured or anchored in place by the introduction of a plurality of individual fasteners, preferably helical fasteners which are rotated and "screwed into" the prosthesis and vessel wall. Fasteners may be placed through the fabric only, i.e., avoiding the scaffold structure. Alternately, the fasteners can be introduced into and through portions of the scaffold structure, optionally through receptacles or apertures which have been specially configured to receive the fasteners. In some cases, of course, fasteners will be introduced both through the fabric and through of over the scaffold structure.

In the exemplary embodiment, the fasteners are helical fasteners, which are introduced singly, i.e., one at a time, in a circumferentially spaced-apart pattern over an interior wall of the prosthesis. Usually, the fasteners will be introduced using a fastener applier which carries a single fastener. Fastener appliers which carry a single fastener can have a lower profile and may be more effective and less traumatic than fastener appliers which carry multiple fasteners. The present invention, however, does contemplate that in certain embodiments the fastener applier may carry multiple fasteners. Moreover, the fastener applier may simultaneously deploy multiple fasteners in the preferred circumferentially spaced-apart space pattern described above. Usually, from 2-12 fasteners will be applied at each end of the prosthesis to be anchored. The 2-12 fasteners will usually be applied in a single circumferentially space-apart row that may be applied in more than one row with individual fasteners being axially

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aligned or circumferentially staggered. In a preferred embodiment, the intraluminal fastener applier of the present invention comprises a guide component and an applier component. The guide component, for example, comprises a tubular body having a deflectable distal tip and, optionally, a stabilizer for holding the deflected tip against a location in the graft to which the fastener is to be applied. The applier component is insertable through a lumen of the guide component and carries at least a single helical or other fastener. A rotation driver is provided for rotating and advancing the helical fastener so that it penetrates the graft and underlying vessel wall to anchor the graft firmly in place.

Brief Description of the Drawings

The invention will be understood from the following detailed description of preferred embodiments, taken in conjunction with the accompanying drawings, wherein:

Fig. 1 is a perspective view of one embodiment of an endovascular graft delivery device shown positioned within an abdominal aortic aneurysm;

Fig. 2 is a perspective view of one embodiment the deployment of an endovascular graft within the aneurysm of Fig. 1;

Fig. 3 is a perspective view of a fully deployed straight endovascular graft of Fig. 2;

Fig. 4 is a perspective view of a fully deployed bifurcated endovascular graft broken away to show an anchoring scaffold at one end;

Fig. 5 is a perspective view similar to Fig. 5 showing an alternative scaffold structure;

Fig. 6 is a perspective view showing one embodiment of a device for directing the fastener applier;

Fig. 7 is a perspective view showing the

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device of Fig. 6 upon insertion within the deployed endovascular graft of Fig. 3 with both the graft and scaffolding broken away;

Fig. 8 is a perspective view of the device of
5 Fig. 6 showing activation of one embodiment of a stabilizing device attached to the directing device;

Fig. 9 is a perspective view of the control assembly in Fig. 8 articulating the directing device of Fig. 6;

10 Fig. 10 is a perspective view of an alternative embodiment of the stabilization device of Fig. 8;

Fig. 11 is a perspective view showing the activation of the alternative stabilization device of
15 Fig. 10;

Fig. 12 is a perspective view showing another embodiment of the stabilization device of Fig. 8;

Fig. 13 is a perspective view showing activation of the stabilization device of Fig. 12;

20 Fig. 14 is one embodiment of the fastener applier;

Fig. 15 is a perspective view of the fastener applier of Fig. 14 being positioned within directing device of Fig. 6;

25 Fig. 16 is an enlarged cross-sectional view of one embodiment of the fastener applier of Fig. 14;

Fig. 17 is an enlarged cross-sectional view of the attachment applier showing one embodiment of the proximal end of the helical fastener and the drive
30 mechanism;

Fig. 18 is a enlarged perspective view of one embodiment of the helical fastener of Fig. 16;

Fig. 19 is an enlarged view of the attachment applier showing one embodiment of the control assembly
35 that activates the fastener applier;

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Fig. 20 is an enlarged view of the attachment applied activated with a fastener implanted into the graft and vessel wall;

Fig. 21 is an enlarged view of the completed
5 attachment of the proximal graft of Fig. 3 to the vessel wall with fasteners;

Fig. 22 is a perspective view of the graft of Fig. 4 completely attached to the vessel.

Detailed Description of the Invention

10 Fig. 1 depicts an endovascular graft delivery catheter 10 being positioned within an abdominal aortic aneurysm 11 over a guidewire 12. Fig. 2 depicts the initial stage of graft deployment within a vessel. The delivery catheter 10 has a movable cover 13 over the
15 graft. When the cover is pulled proximally the graft 14 expands to contact the internal walls of the vessel. It is contemplated that the graft could be self-expanding or utilize an expanding member such as a balloon or mechanical expander. The process of graft deployment is
20 continued until the graft is fully deployed within the vessel. It is contemplated that the graft could be in either a straight or bifurcated form. Fig. 3 depicts a completely deployed straight graft 14 and Fig. 4 depicts a completely deployed bifurcated graft 15. The guidewire
25 11 used to deliver and position the graft remains within the vessel for access of the fastener attachment system. One embodiment of the graft scaffolding 16 (stent) is illustrated in the area broke away in Fig. 4. The stent is in the form of a simple zigzag pattern, however it is
30 contemplated that the stent design could involve more complex patterns 17 as depicted in Fig. 5. Although only one stent structure within the graft is depicted, in Fig. 4 and 5, it is contemplated that multiple independent stent structures could be incorporated into the graft.
35 1391 Fig. 6 depicts one embodiment of the directing

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device 18 with an obturator 19 positioned within the lumen of the directing device and extending past the distal of the tip of the directing device. The obturator has a lumen to allow for delivery over a guidewire. Fig. 5 7 depicts the directing device being positioned within the deployed endovascular graft over a Guidewire 12. The directing device has an incorporated stabilizing device 20 to aid in maintaining position of the directing device within the vessel. In one embodiment, the stabilizing device 20 is spring-loaded and is positioned for use when the obturator in the directing device is removed Fig. 8. The directing device is activated through a control assembly 21 as seen in Fig. 8. In one embodiment the control assembly 21 features a movable wheel or lever 22, 15 which deflects the distal tip 23 of the directing device 18 to the desired location as seen in Fig. 9. It is contemplated that the control assembly for the directing device could be activated mechanically, electrically, hydraulically or pneumatically. The control assembly has 20 a through lumen to allow for the passage of the obturator and fastener applier. Fig. 10 depicts another embodiment the stabilizing device as a movable strut assembly 24. The movable strut assembly is activated through a lever 25 on the control assembly Fig. 11. In both embodiments 25 (Fig. 7 and 10) the stabilizing device is distal to the end of the directing device. In another embodiment the stabilizing device could be in the form of an expandable member 26 adjacent to the distal tip of the directing device Fig. 12. In one embodiment, the expandable member 30 26 is shown activated through a lever 25 on the control assembly Fig. 13. However it also contemplated that this type of stabilizing device could also be inflatable. In all embodiments the stabilizing device could be use to stabilize the directing member either concentrically or 35 eccentrically within the vessel.

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In another embodiment of the invention a separate tubular device could be used in cooperation with the directing device and to access the vessel. This separate tubular device could incorporate the stabilizing
5 devices used above with the directing device.

Fig. 14 depicts one embodiment of the fastener applier 27. Fig. 14A is a detail view of the distal end of the fastener applier. Fig. 15 depicts the fastener applier being positioned through the lumen of the
10 directing device to the site where a fastener will be installed.

Fig. 16 is an enlarged cross-sectional view of fastener applier 27 and directing device 18. In one embodiment of the fastener applier the helical fastener
15 28 is rotated via a fastener driver 29 through a drive shaft 30 that is connected to the control assembly 31. The drive shaft 30 can be made of any material that allows for both bending and rotation. The drive shaft is connected to the fastener driver 29, which engages and
20 imparts torque to the helical fastener. Fig. 16 illustrates the coils of the helical fastener 28 engaged with internal grooves 32 within the fastener applier. It is contemplated that the grooves could be positioned along the entire length of the fastener or within a
25 portion of its length. Fig. 17 is an enlarged cross-sectional view of the fastener applier 27 with a cross-section of the fastener driver 29 depicting one embodiment of engagement between the fastener driver and helical fastener 28. In this embodiment the proximal coil
30 of the helical fastener is formed to produce a diagonal member 33, which crosses the diameter of the helical fastener. Similar helical fasteners are described in U.S. Patent No. 5,964,772; 5,824,008; 5,582,616; and 6,296,656, the full disclosures of which are incorporated
35 herein by reference.

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Fig. 18 depicts one embodiment of the helical fastener 28 showing the diagonal member 33. Fig. 19 depicts one embodiment of the fastener applier 27 during activation of the fastener applier control assembly.

5 Activation of the control assembly rotates the drive shaft, faster driver and helical fastener. This rotation causes the helical fastener 28 to travel within the internal grooves 32 of the fastener applier and into the graft 14 and vessel wall 34 Fig. 20. It is contemplated

10 that the control assembly for the fastener applier could be activated mechanically, electrically, hydraulically or pneumatically.

Fig. 21 illustrates a completed helical fastener 28 attachment of the graft 14 to the vessel wall

15 34. It is contemplated that one or more fasteners will be required to provide secure attachment of the graft to the vessel wall.

Fig. 22 illustrates a perspective view of a graft prosthesis attached to the vessel wall both

20 proximally and distally. It is contemplated that the present invention can be used for graft attachment of both straight and bifurcated grafts 15 within the aorta and other branch vessels.

It will be appreciated that the components

25 and/or features of the preferred embodiments described herein may be used together or separately, while the depicted methods and devices may be combined or modified in whole or in part. It is contemplated that the components of the directing device, fastener applier and

30 helical fastener may be alternately oriented relative to each other, for example, offset, bi-axial, etc. Further, it will be understood that the various embodiments may be used in additional procedures not described herein, such as vascular trauma, arterial dissections, artificial

35 heart valve attachment and attachment of other prosthetic

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device within the vascular system and generally within the body.

The preferred embodiments of the invention are described above in detail for the purpose of setting
5 forth a complete disclosure and for the sake of explanation and clarity. Those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

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WHAT IS CLAIMED IS:

1. A method for implanting a radially expandable prosthesis in a body lumen, said method comprising:

5 expanding at least one scaffold of the prosthesis at an implantation site within the body lumen; and

 introducing a plurality of fasteners through the prosthesis in the region of the scaffold to anchor
10 the scaffold in place.

2. A method as in claim 1, wherein the scaffold is elastic and expanding comprises releasing the scaffold from constraint to permit the scaffold to self expand at the implantation site.

15 3. A method as in claim 1, wherein the scaffold is malleable and expanding comprises applying a radially expansive force within the scaffold to cause expansion.

 4. A method as in claim 1, wherein expanding
20 comprises expanding at least to scaffolds at spaced apart locations on the prosthesis

 5. A method as in claim 1, wherein expanding comprises expanding at least three spaced apart prostheses on the prosthesis.

25 6. A method as in claim 1, wherein expanding comprises expanding a scaffold structure that spans the entire length of the prosthesis.

 7. A method as in claim 1, wherein the prosthesis comprises a fabric covering at least a portion
30 of the scaffold, wherein introducing comprises introducing at least some of the fasteners through the fabric but not through the scaffold.

 8. A method as in claim 1, wherein the prosthesis comprises a fabric covering at least a portion
35 of the scaffold, wherein introducing comprises

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introducing at least some of the fasteners over elements of the scaffold.

9. A method as in claim 1, wherein the fasteners are helical penetrating fasteners.

5 10. A method as in claim 9, wherein the introducing step comprises introducing single fasteners in a circumferentially spaced-apart pillar on the inner wall of the prosthesis.

10 11. A method as in claim 10, wherein introducing comprises introducing from two to 12 helical fasteners at each region where the fasteners are placed.

12. An intraluminal fastener applier comprising:

15 a tubular body with a deflectable distal end;
a stabilizer configured to engage a blood vessel wall to hold the distal end of

tubular body in place;

20 a control handle at a proximal end of the tubular body having controls to separately deflect the distal end, and deploy the stabilizer that holds the deflected distal end in place;

and means to advance a fastener from the distal end into the blood vessel wall engaged by the distal end.

25 13. An intraluminal fastener applier as in claim 12, wherein the fastener advancing means comprises a fastener delivery device which is introducable through the tubular body and which carries at least one fastener.

30 14. An intraluminal fastener applier as in claim 13, wherein the fastener delivery device comprises a flexible shaft which carries a single helical fastener at its distal end and a means for rotating and advancing the helical fastener to penetrate tissue.

35 15. An intraluminal fastener as in claim 14, wherein the flexible shaft has a helical track which

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carries the helical fastener and a rotator wire that engages and rotates the helical fastener to cause advancement from the distal end of the body.

16. A method for implanting a radially
5 expandable prosthesis at a target site in a body lumen, said method comprising:

advancing a guidewire from a remote access site to the target site;

10 introducing a prosthesis deployment catheter over the guidewire to the target site;

deploying the prosthesis from the deployment catheter at the target site;

15 exchanging the deployment catheter for an intraluminal fastener applier over the guidewire; and

introducing from the intraluminal fastener applier a plurality of fasteners through the prosthesis to anchor the prosthesis.

17. A method as in claim 16, wherein the prosthesis is self-expanding and deploying comprises
20 releasing the prosthesis from constraint to permit the prosthesis to self-expand at the target site.

18. A method as in claim 16, wherein the prosthesis is malleable and expanding comprises applying a radially expansive force within the prosthesis to cause
25 expansion.

19. A method as in claim 16, wherein a single fastener is applied from the intraluminal fastener applier and the applier is withdrawn from the vasculature and a new fastener loaded on the catheter before
30 returning the applier to the target location.

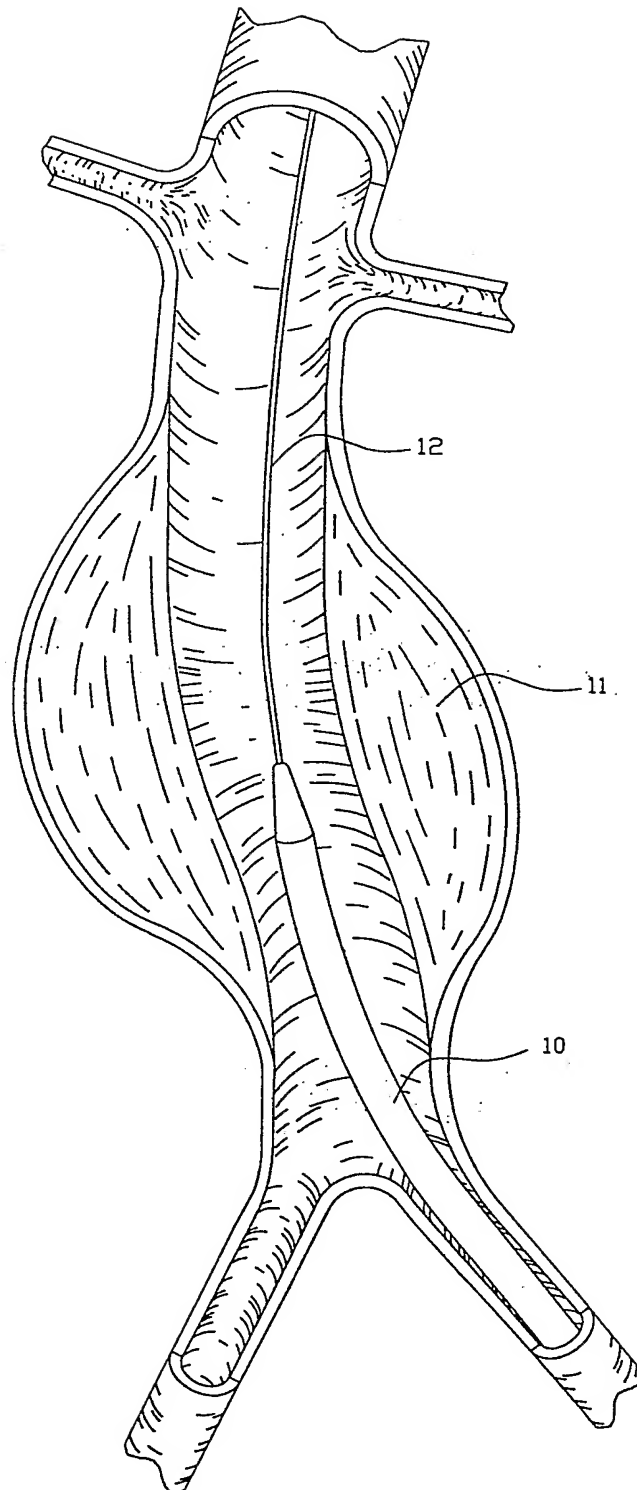


Fig. 1

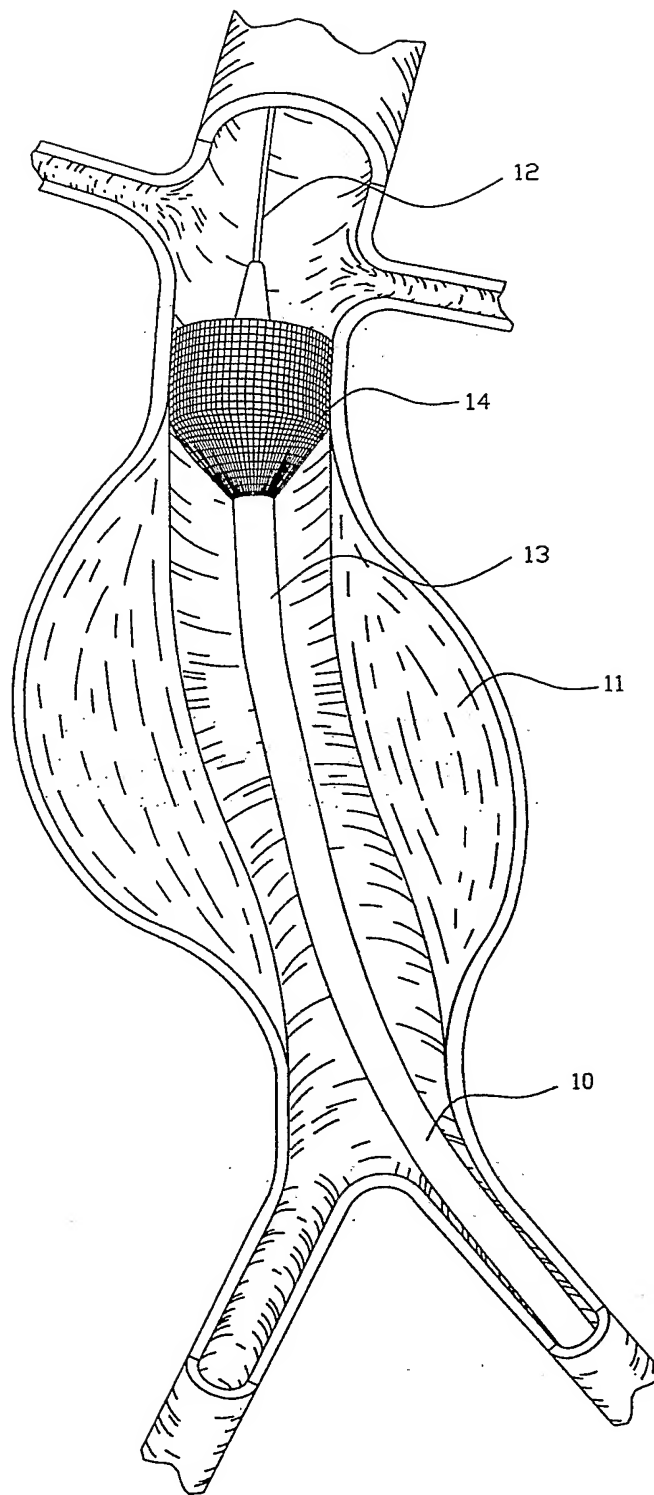


Fig. 2

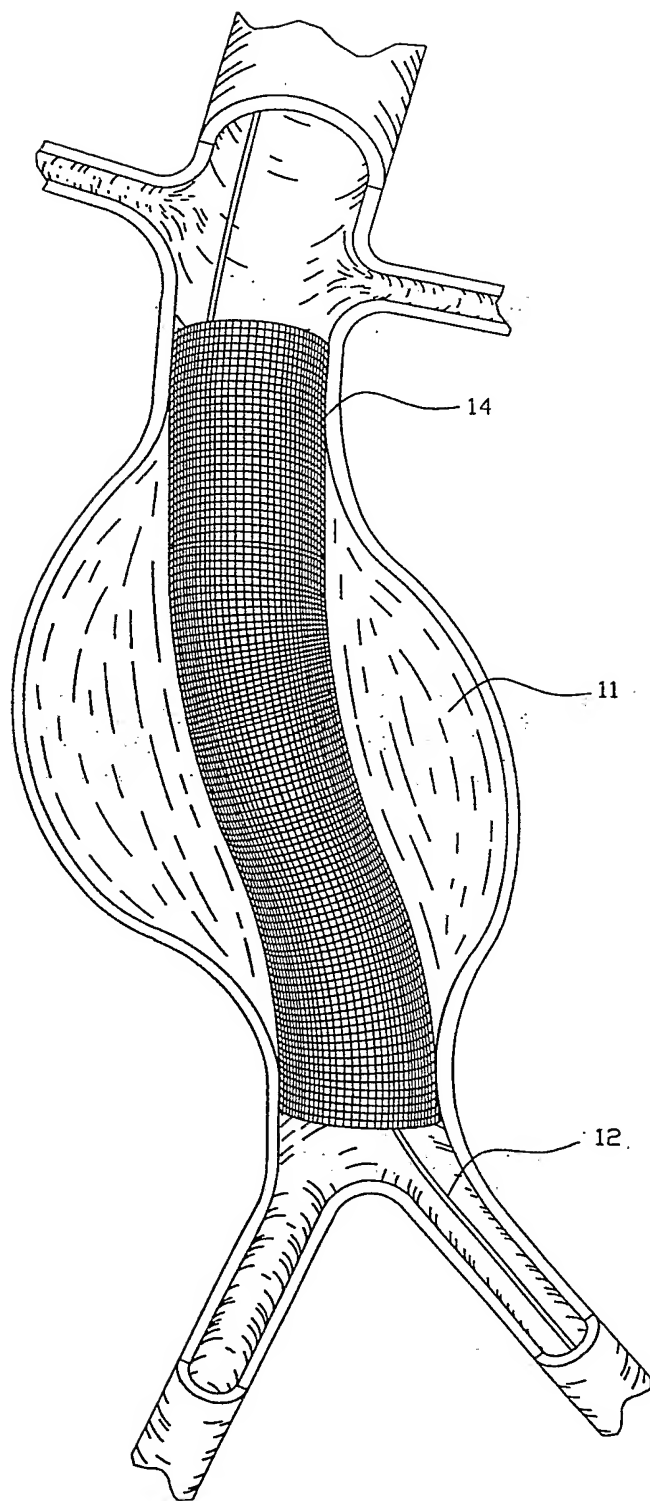


Fig. 3

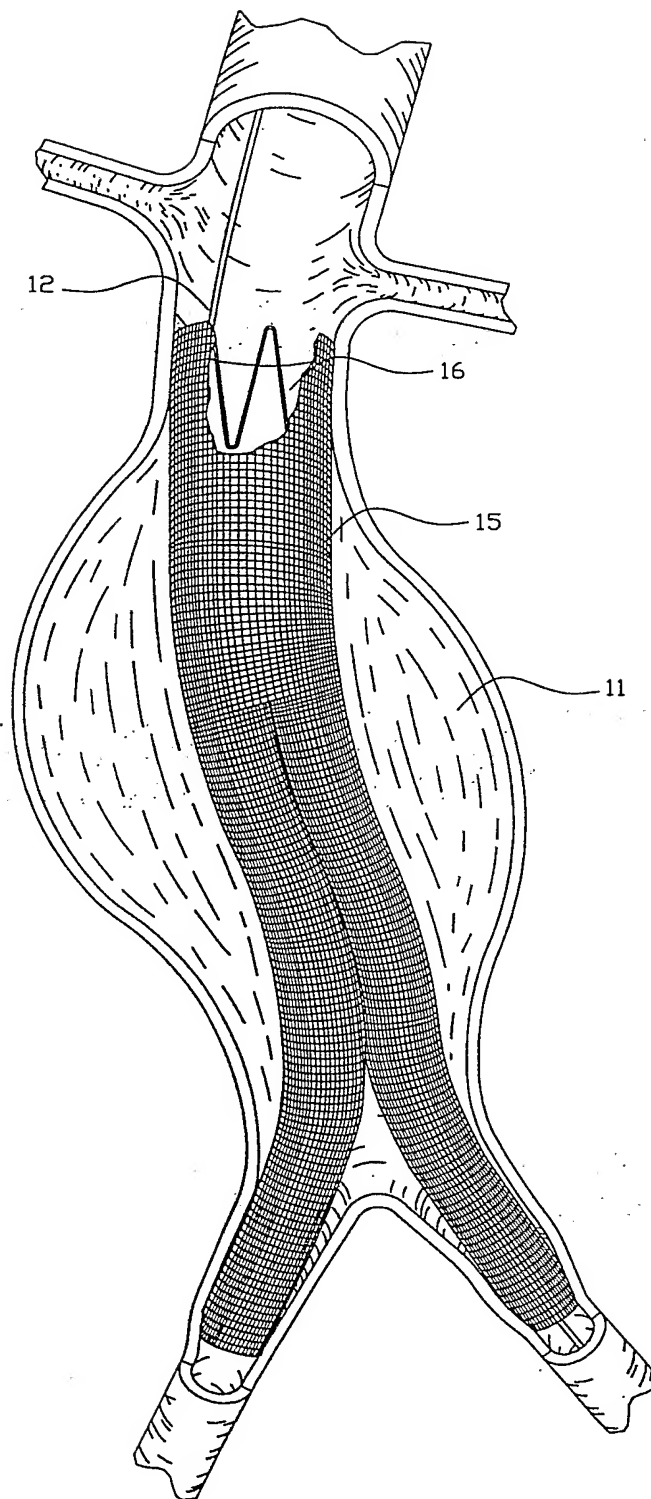


Fig. 4

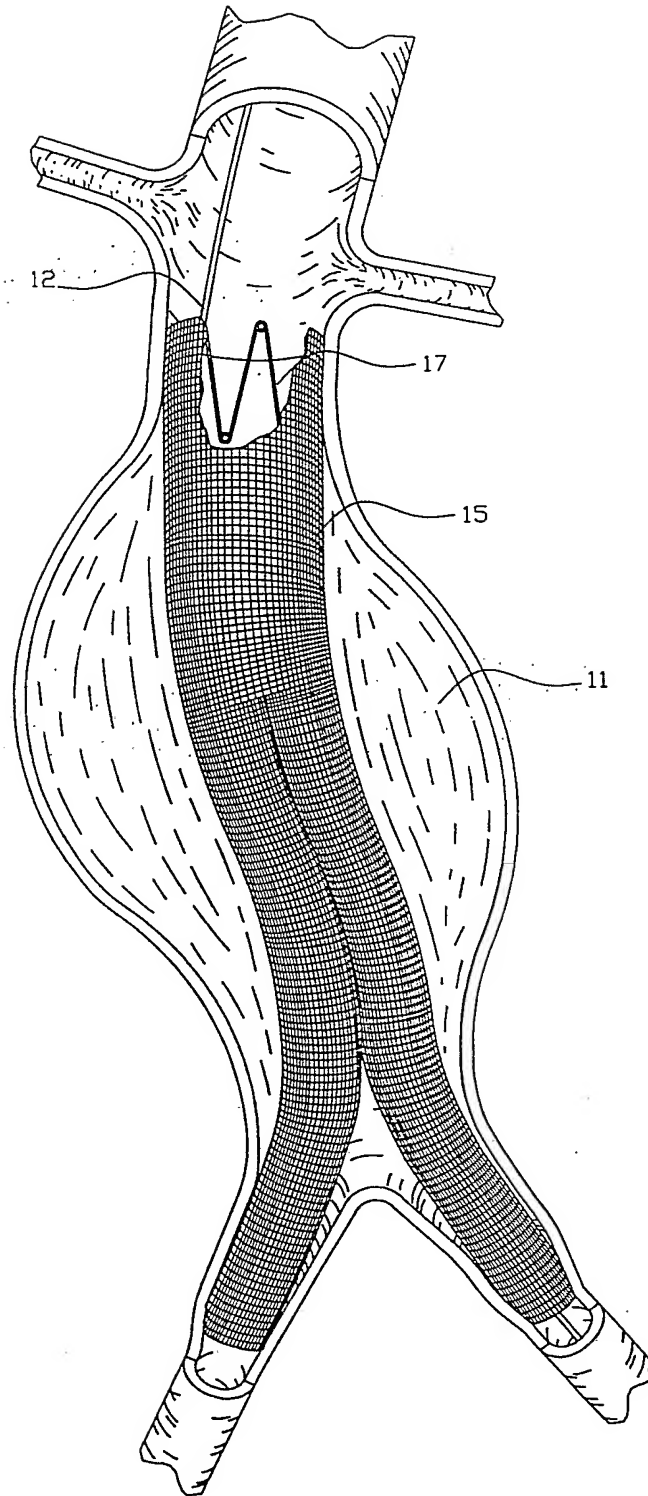


Fig. 5

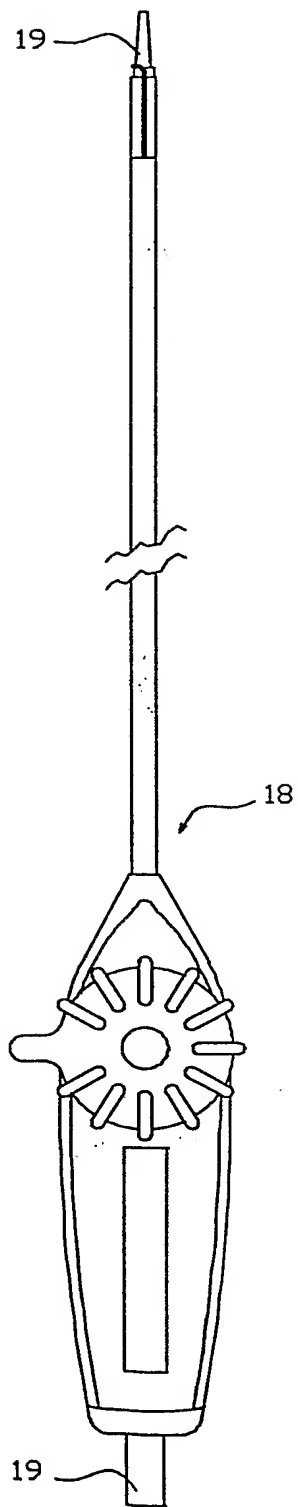


Fig. 6

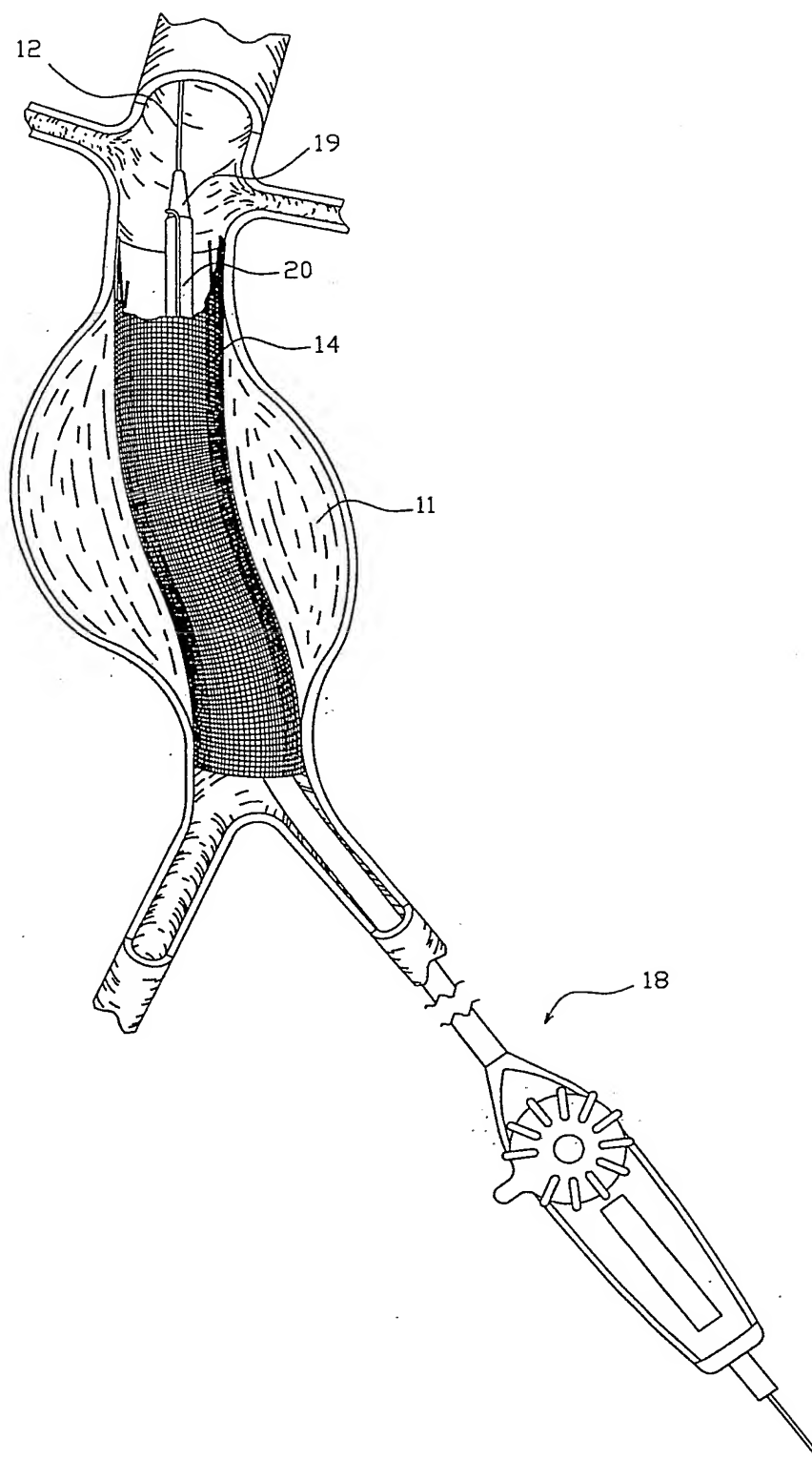


Fig. 7

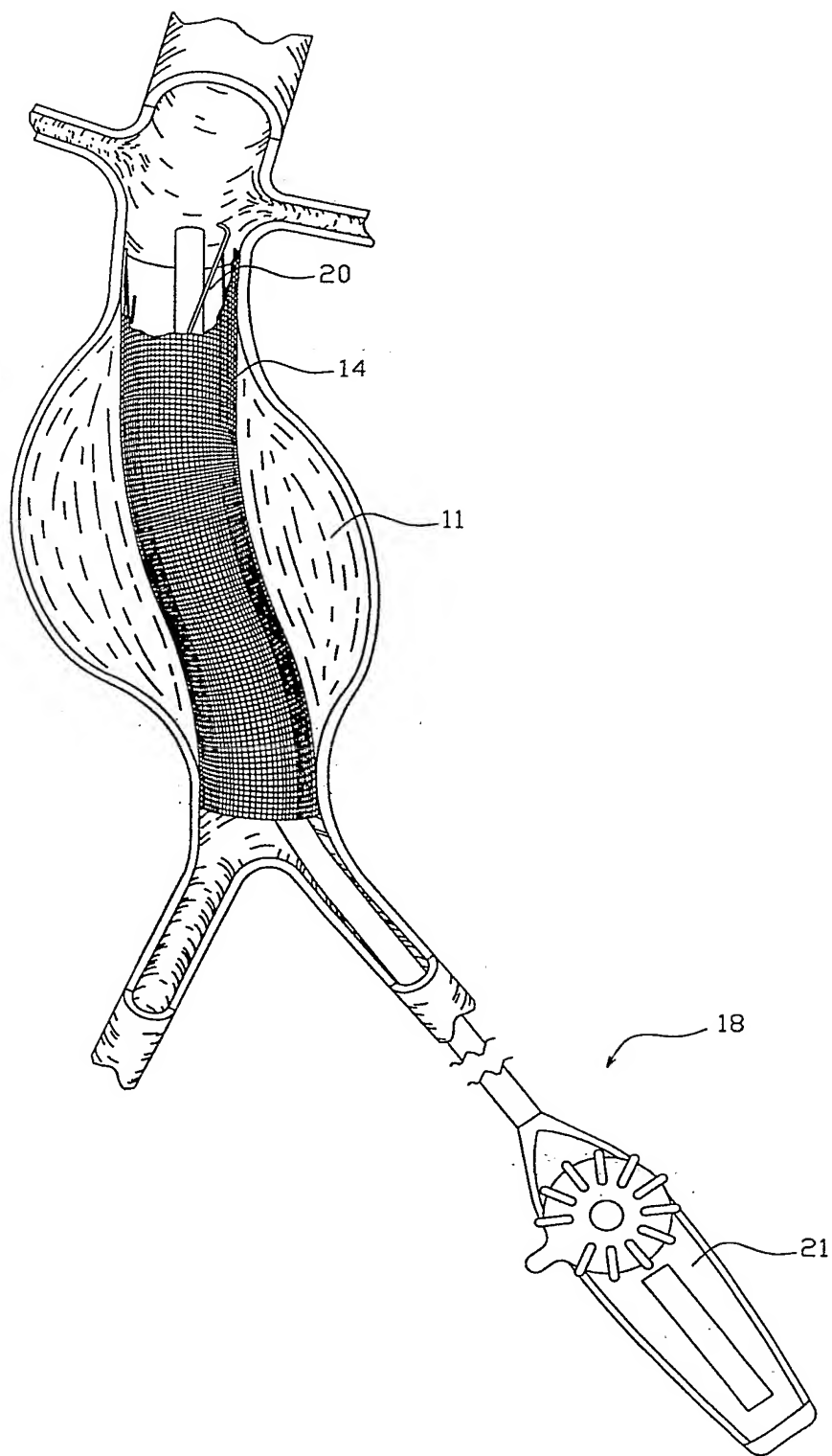


Fig. 8

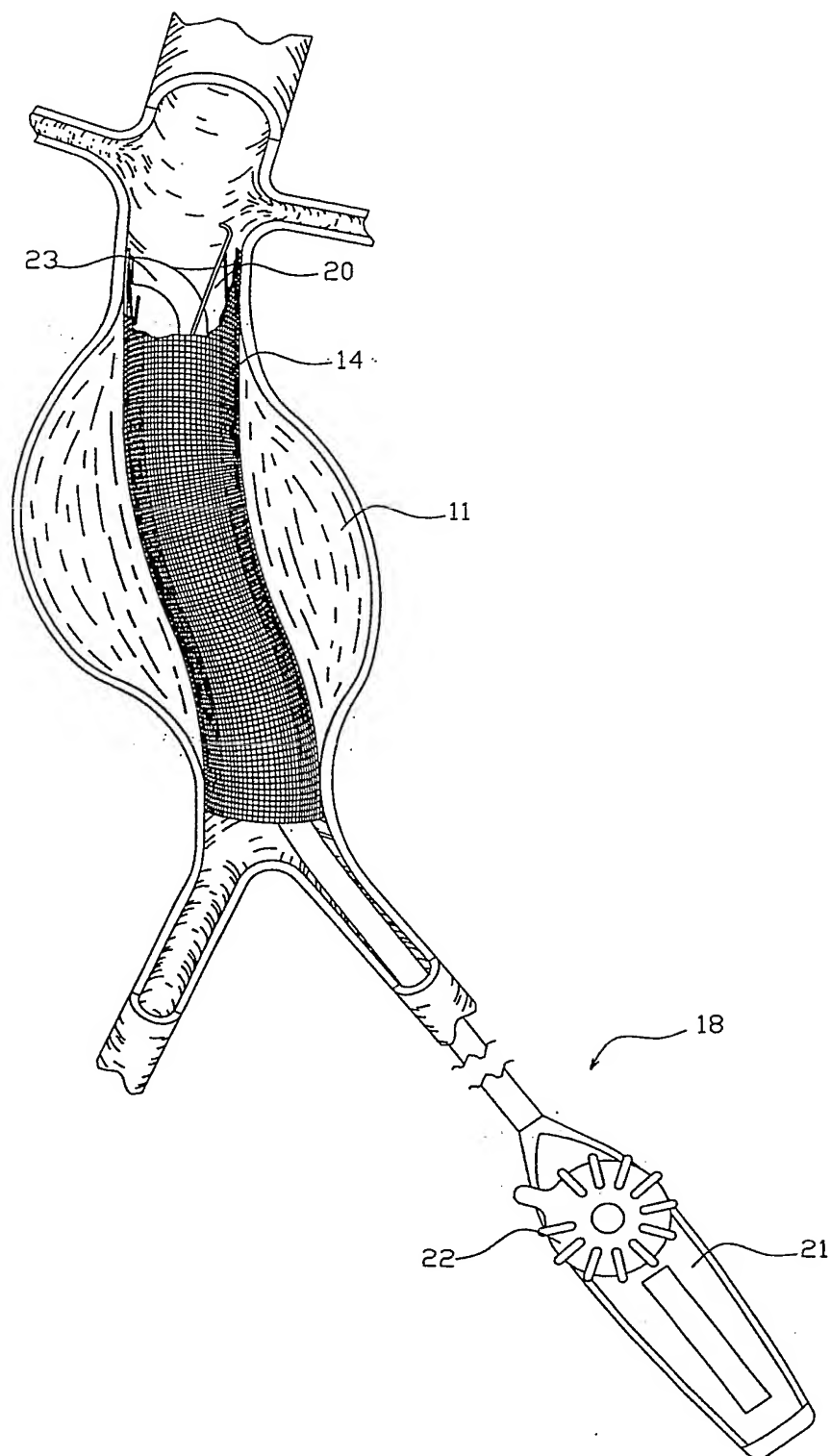


Fig. 9

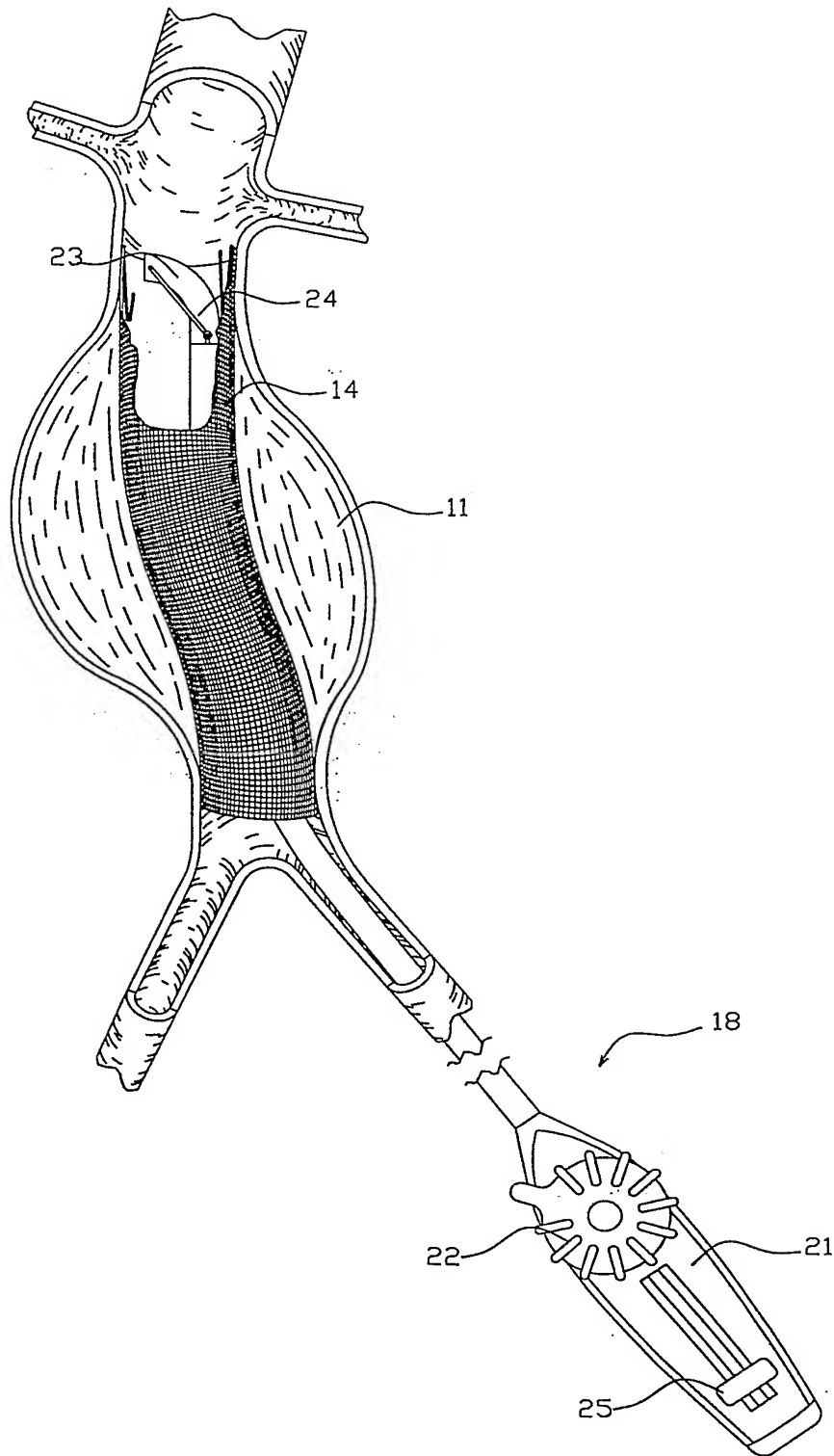


Fig. 10

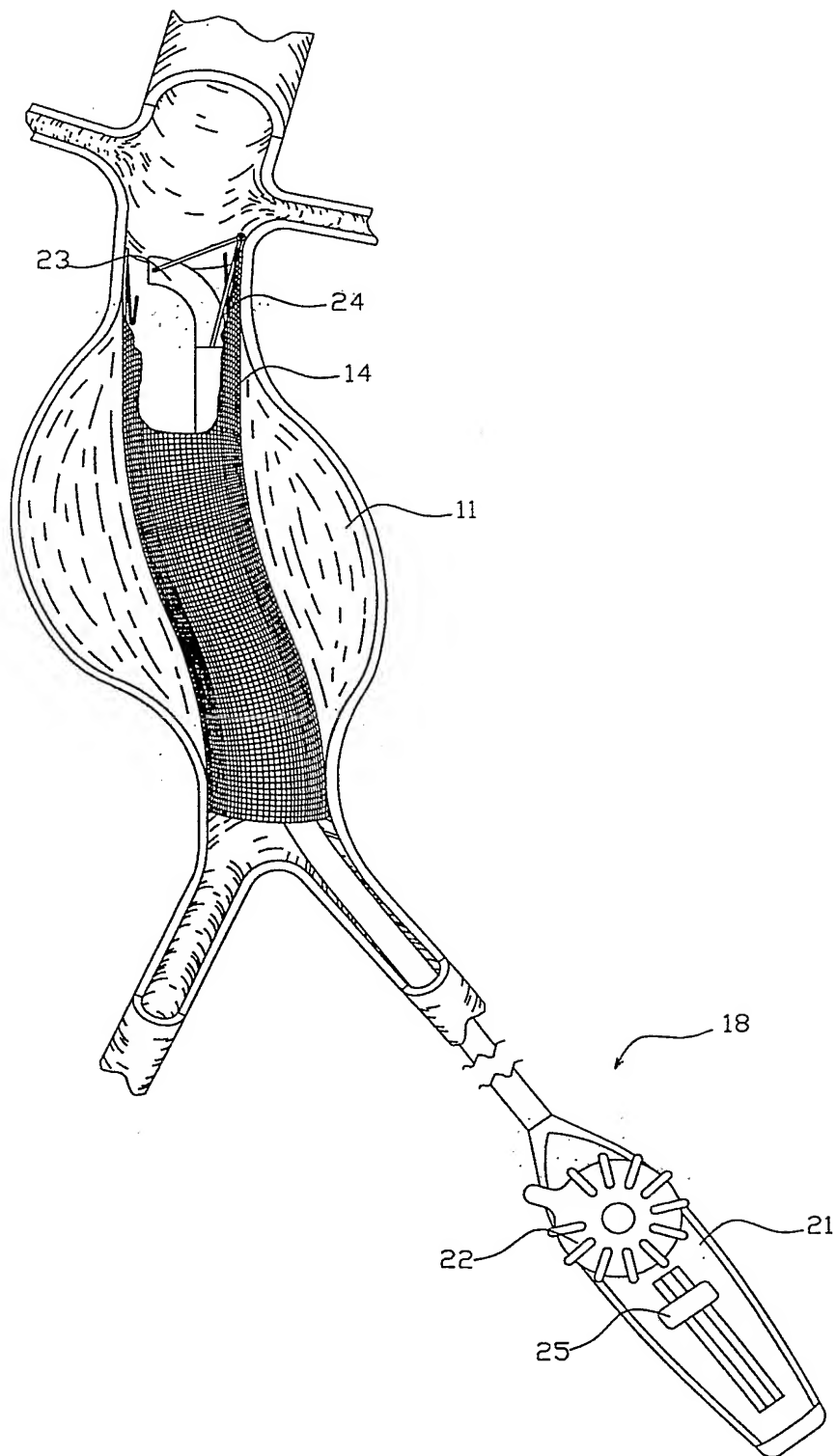


Fig. 11

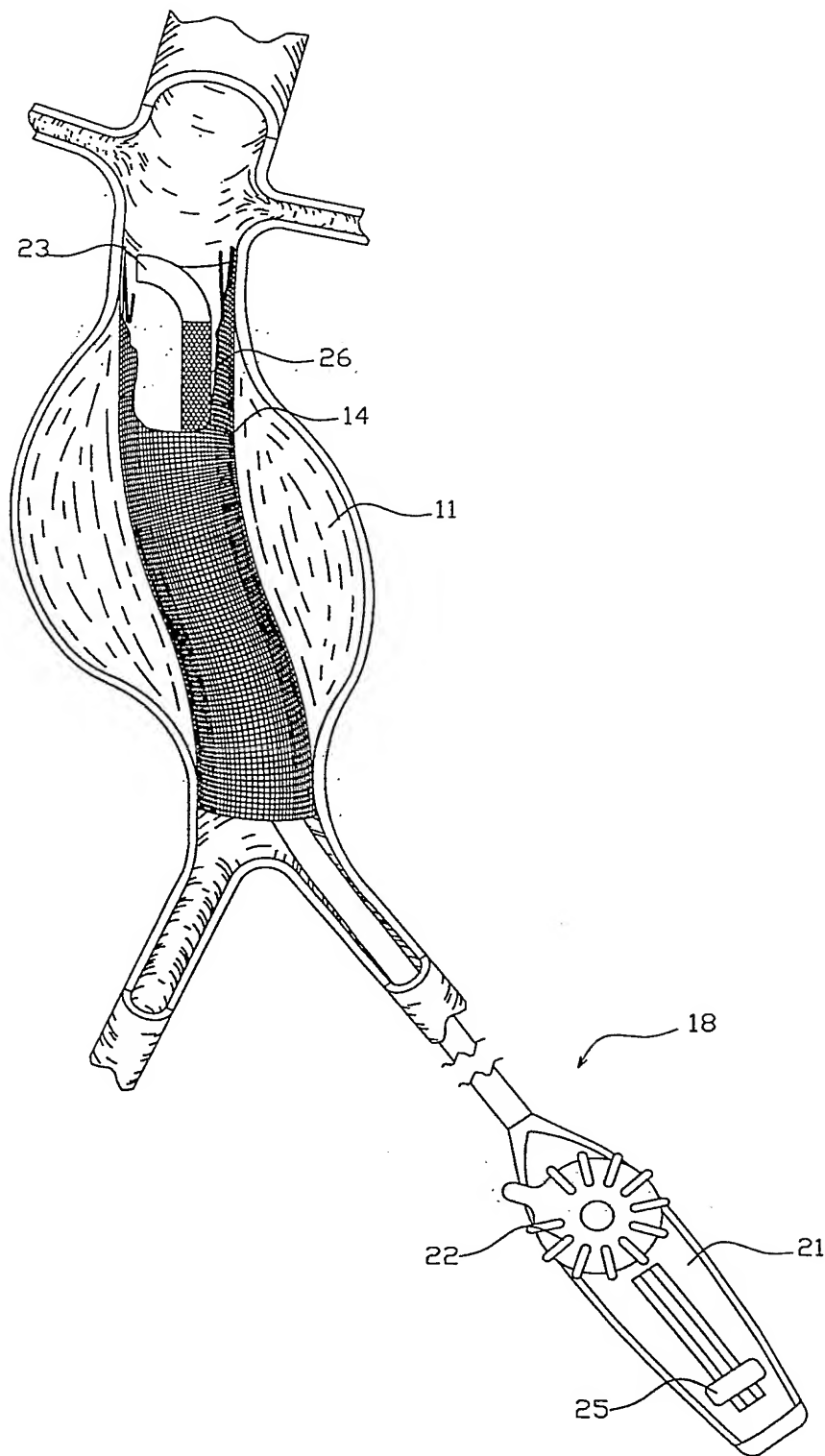


Fig. 12

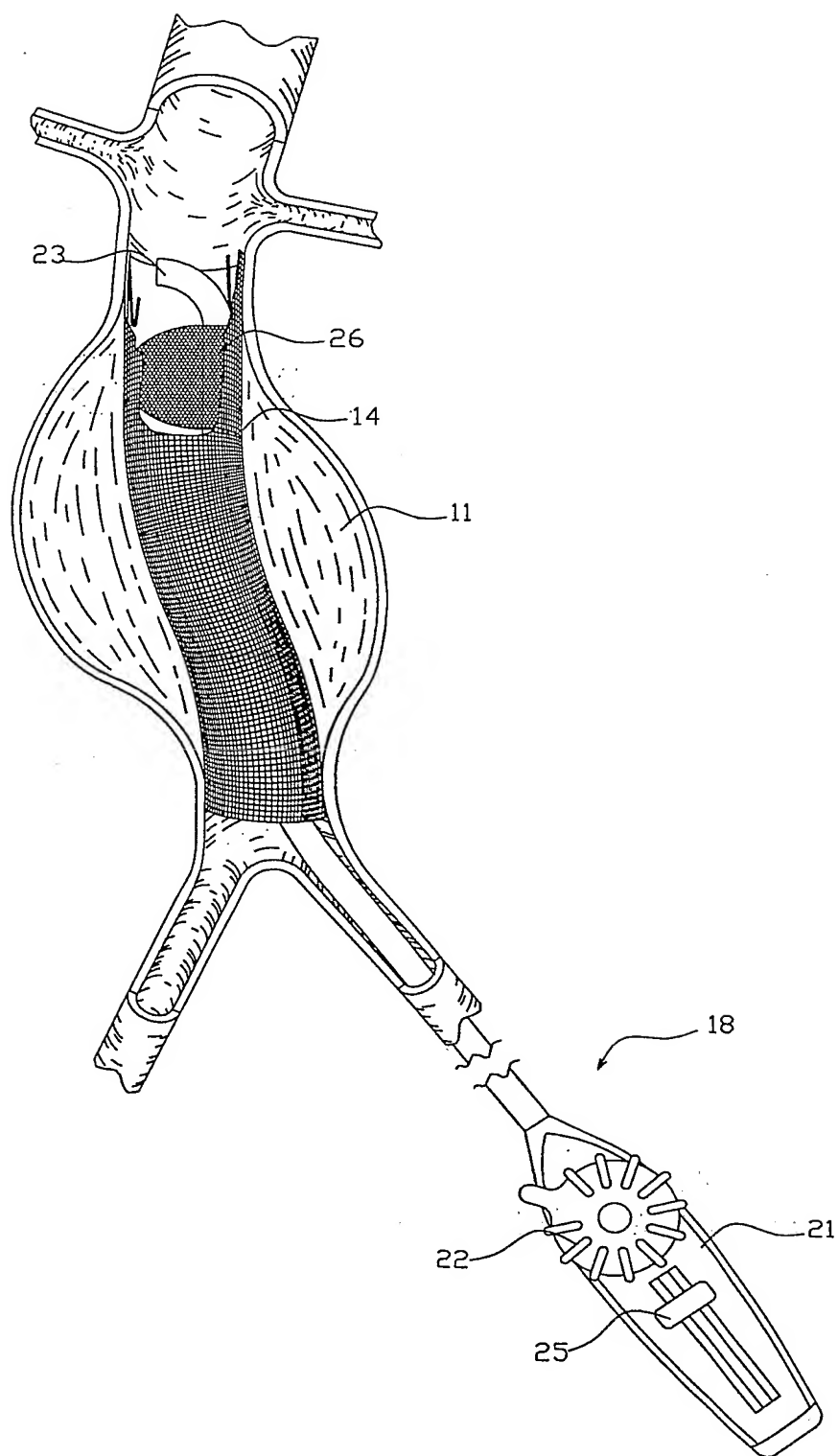


Fig. 13

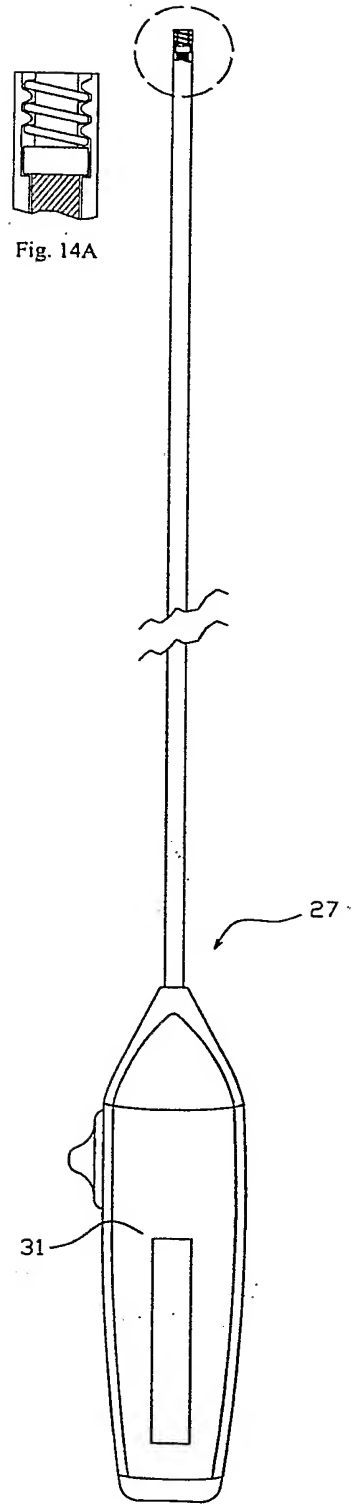


Fig. 14

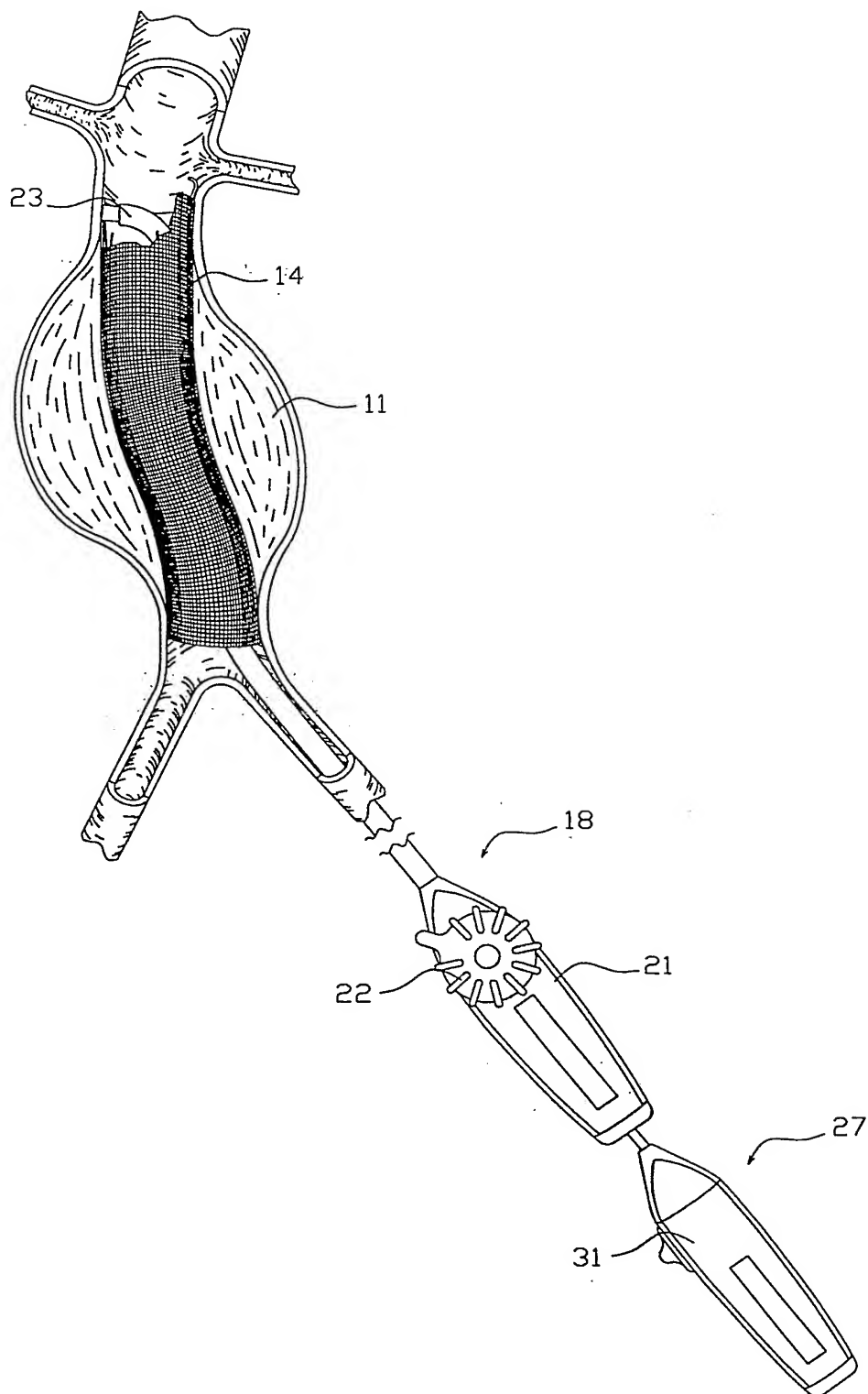


Fig. 15

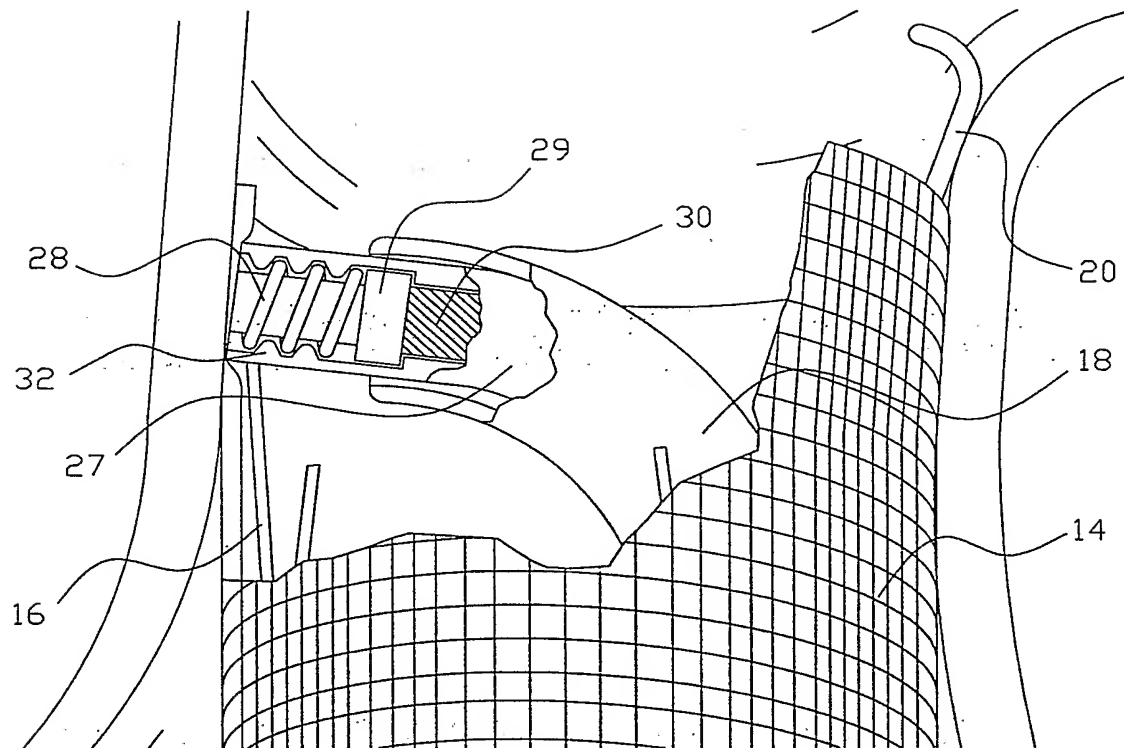


Fig. 16

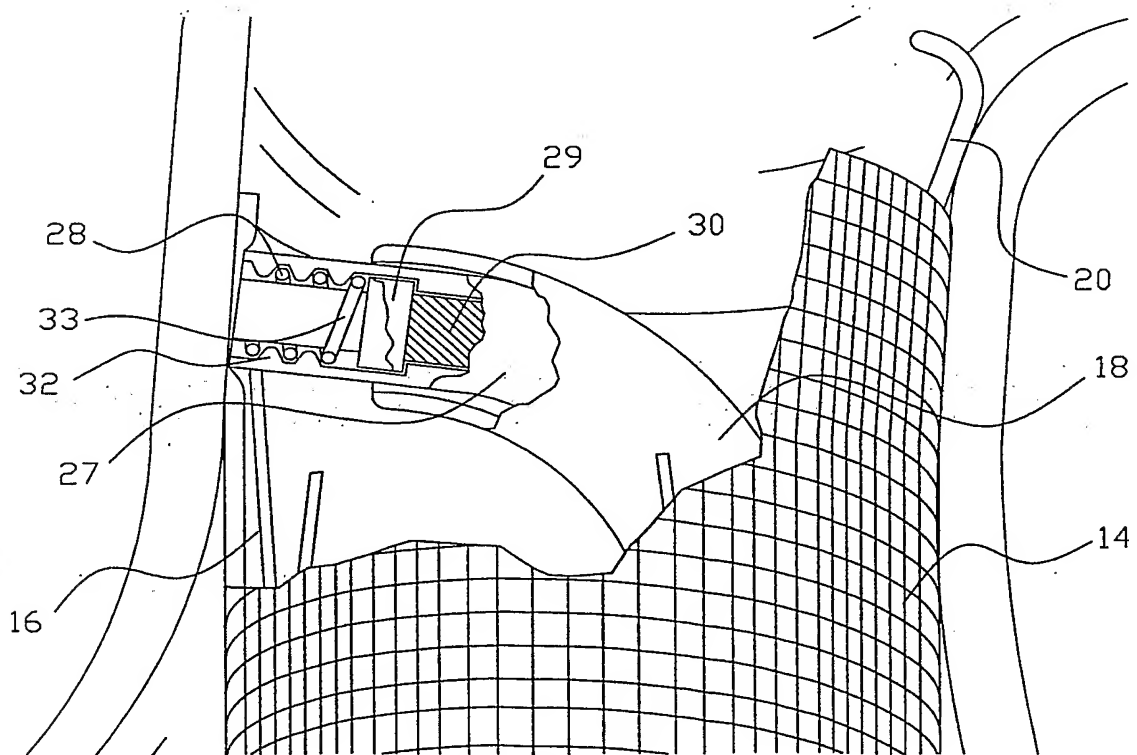


Fig. 17

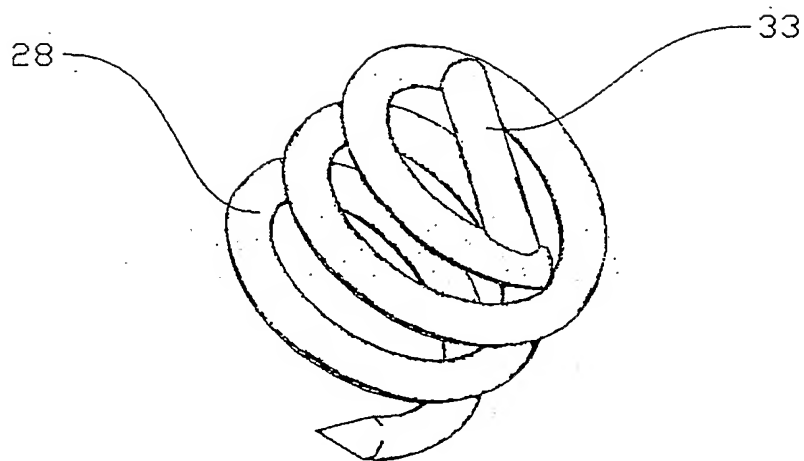


Fig. 18

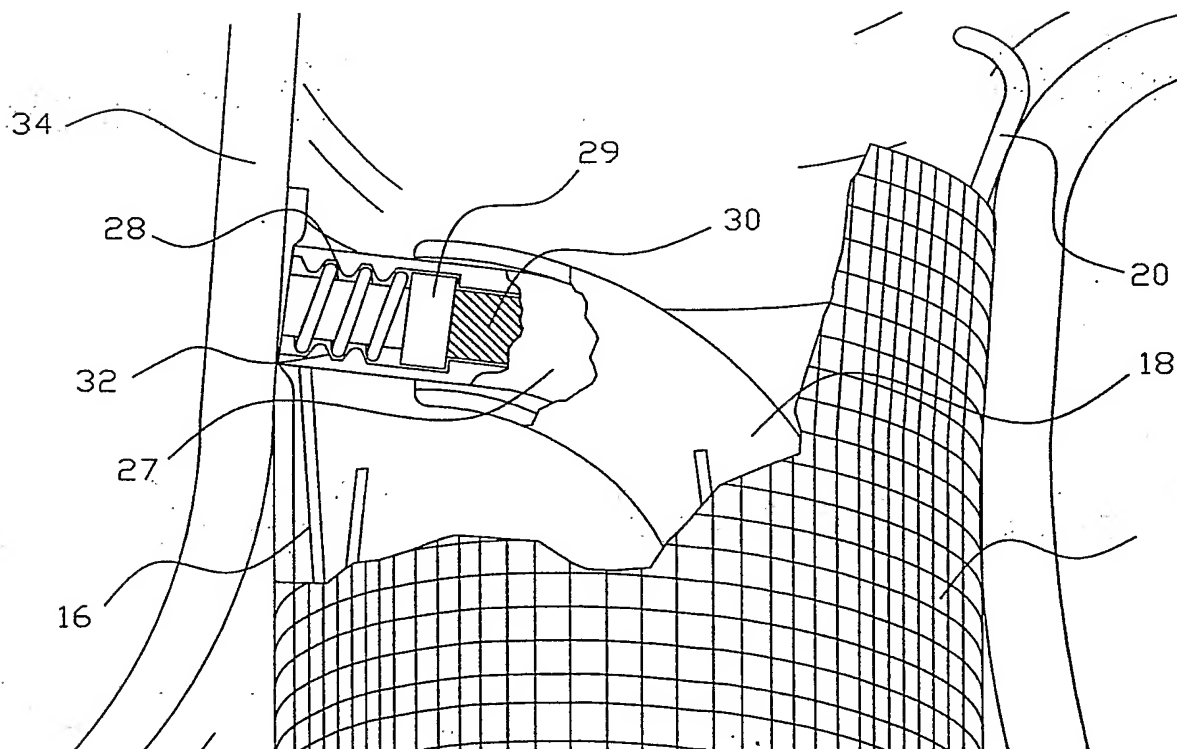


Fig. 19

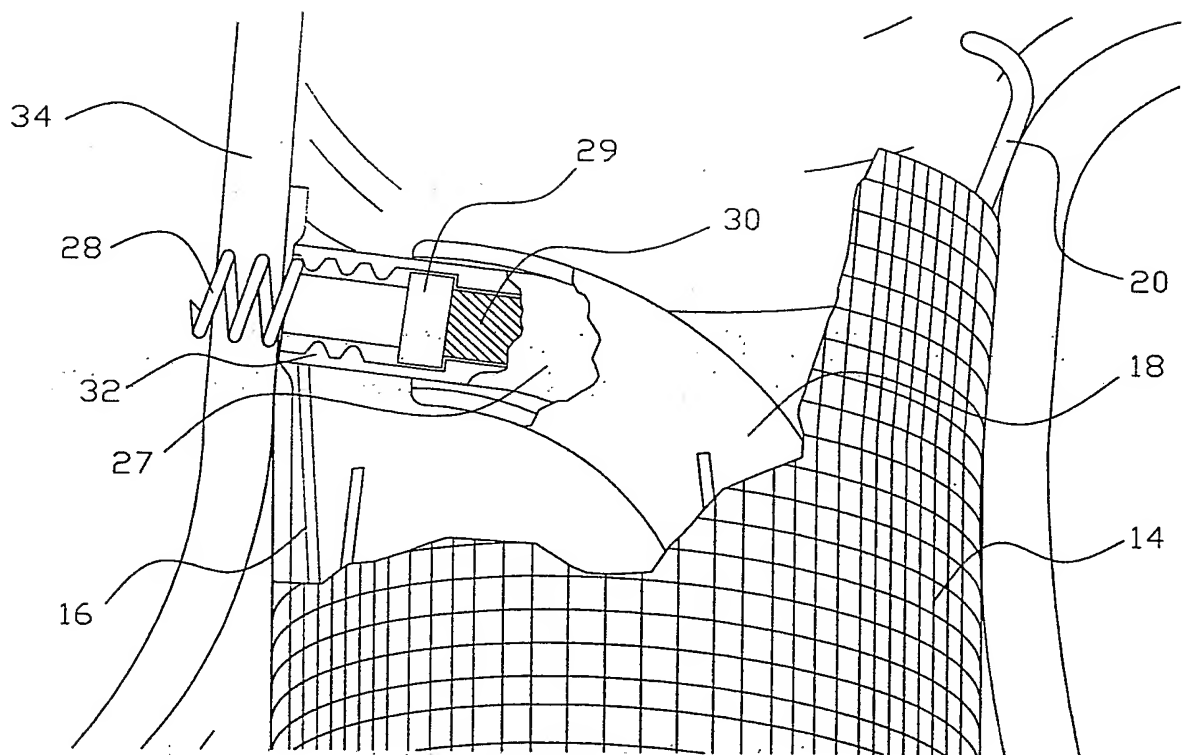


Fig. 20

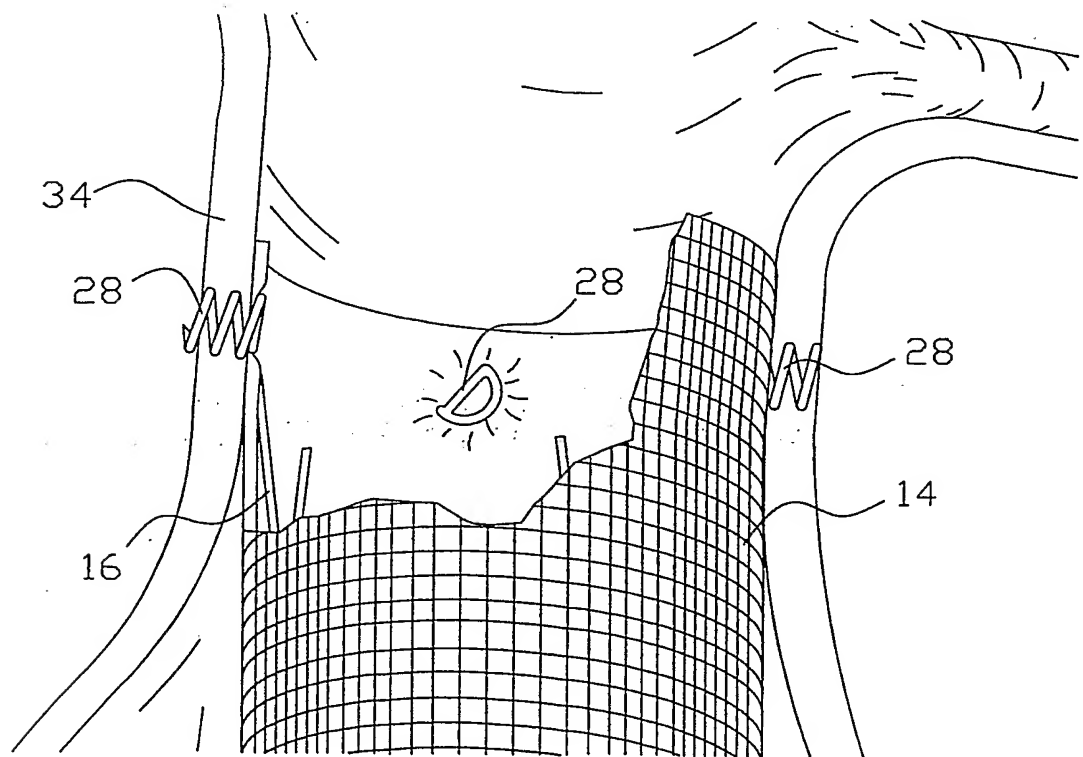


Fig. 21

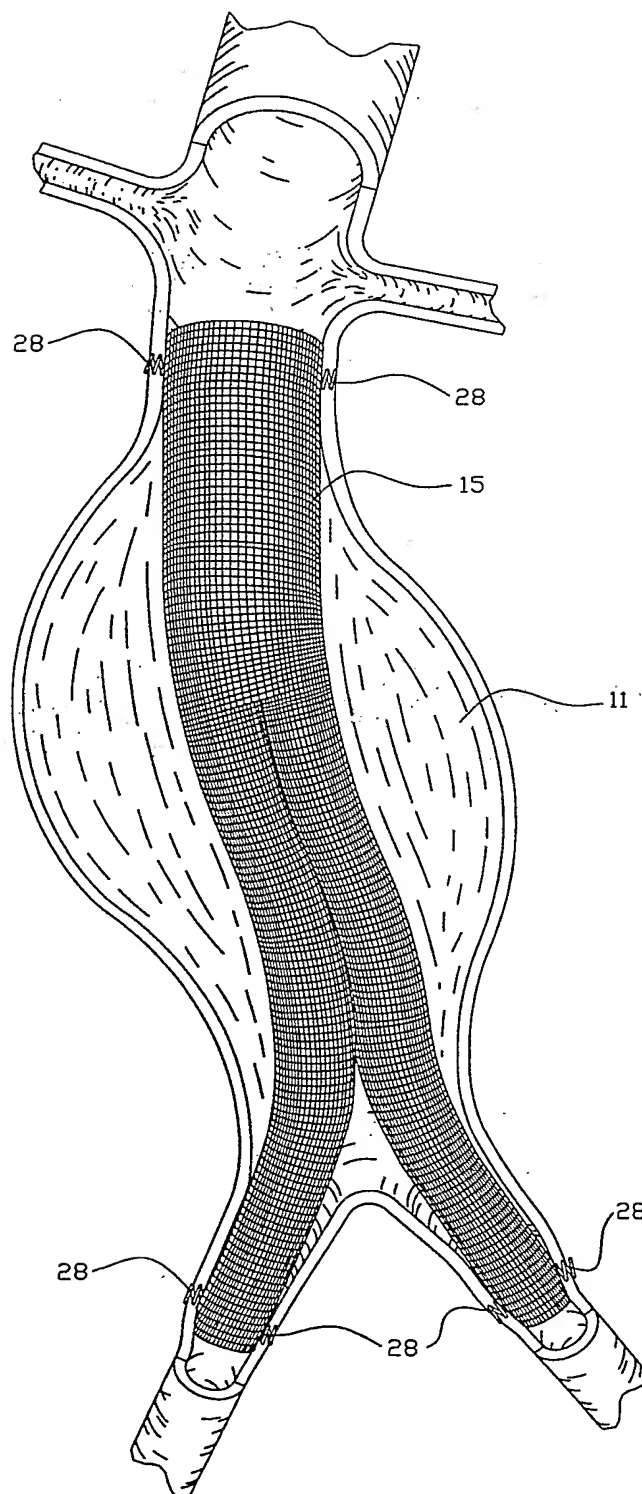


Fig. 22

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/32753

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61F 2/06

US CL :623/1.36

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 623/1.36, 1.11

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,207,695 A (TROUT, III) 04 MAY 1993, COL. 5, LINE 6 TO COL. 6, LINE 19.	1-11, 16-19
X	US 6,086,582 A (ALTMAN ET AL.) 11 JULY 2000, FIGURES 1a and 1c.	12-15



Further documents are listed in the continuation of Box C.



See patent family annex.

"A"	document defining the general state of the art which is not considered to be of particular relevance	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E"	earlier document published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
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"O"	document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
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WO 03/045467 A2

(54) Title: INTRALUMINAL PROSTHESIS ATTACHMENT SYSTEMS AND METHODS

(57) Abstract: Systems and method implant prostheses in the body. The systems and methods provide permanent attachment of the prosthesis in the body. The prosthesis can comprise, e.g., an endovascular graft, which can be deployed without damaging the native blood vessel in either an arterial or a venous system. The endovascular graft can comprise, e.g., a radially expanding vascular stent and/or a stent-graft. The graft can be placed in the vasculature, eg., to exclude or bridge an aneurysm, for example, an abdominal aortic aneurysms. The graft desirably adapts to changes in aneurysm morphology and repairs the endovascular aneurysm. The fastening systems and methods can be deployed through the vasculature and manipulated from outside the body, to deliver a fastener to attach the graft to the vessel wall.

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INTRALUMINAL PROSTHESIS ATTACHMENT SYSTEMS AND METHODS
Related Application

This application claims the benefit of co-pending United States Patent Application Serial No. 10/271,334, filed October 15, 2002. This application
5 also claims the benefit of co-pending United States Provisional Application Serial No. 60/333,937 filed 28 November 2001.

Background of the Invention

10 The invention relates generally to the attachment of a vascular prosthesis to a native vessel, and in particular, to a method and system of devices for the repair of diseased and/or damaged sections of a vessel.

15 The weakening of a vessel wall from damage or disease can lead to vessel dilatation and the formation of an aneurysm. Left untreated, an aneurysm can grow in size and may eventually rupture.

For example, aneurysms of the aorta primarily
20 occur in abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation. Aneurysms can also occur in the thoracic region between the aortic arch and renal arteries. The rupture of an aortic aneurysm results in massive hemorrhaging and has a
25 high rate of mortality.

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Open surgical replacement of a diseased or damaged section of vessel can eliminate the risk of vessel rupture. In this procedure, the diseased or damaged section of vessel is removed and a prosthetic graft, made either in a straight or bifurcated configuration, is installed and then permanently attached and sealed to the ends of the native vessel by suture. The prosthetic grafts for these procedures are usually unsupported woven tubes and are typically made from polyester, ePTFE or other suitable materials. The grafts are longitudinally unsupported so they can accommodate changes in the morphology of the aneurysm and native vessel. However, these procedures require a large surgical incision and have a high rate of morbidity and mortality. In addition, many patients are unsuitable for this type of major surgery due to other co-morbidities.

Endovascular aneurysm repair has been introduced to overcome the problems associated with open surgical repair. The aneurysm is bridged with a vascular prosthesis, which is placed intraluminally. Typically these prosthetic grafts for aortic aneurysms are delivered collapsed on a catheter through the femoral artery. These grafts are usually designed with a fabric material attached to a metallic scaffolding (stent) structure, which expands or is expanded to contact the internal diameter of the vessel. Unlike open surgical aneurysm repair, intraluminally deployed grafts are not sutured to the native vessel, but rely on either barbs extending from the stent, which penetrate into the native vessel during deployment, or the radial expansion force of the stent itself is utilized to hold the graft in position. These graft attachment means do not provide the same level of attachment when compared to suture and can damage the native vessel upon deployment.

Summary of the Invention

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The invention provides systems and methods for implanting prostheses in the body. The systems and methods provide permanent attachment of the prosthesis in the body. The prosthesis can comprise, e.g., an
5 endovascular graft, which can be deployed without damaging the native blood vessel in either an arterial or a venous system. The endovascular graft can comprise, e.g., a radially expanding vascular stent and/or a stent-graft. The graft can be placed in the vasculature, e.g.,
10 to exclude or bridge an aneurysm, for example, an abdominal aortic aneurysm. The graft desirably adapts to changes in aneurysm morphology and repairs the endovascular aneurysm. The fastening system and methods are deployed through the vasculature and manipulated from
15 outside the body, to deliver a fastener to attach the graft to the vessel wall.

One aspect of the invention provides a fastener applier for a prosthesis. The applier comprises a drive mechanism sized and configured to be releasably
20 coupled to the fastener to deploy the fastener into the prosthesis. The applier also includes an actuator for the drive mechanism including a sensing mechanism that enables operation of the drive mechanism in response to at least one of (i) a force sensed at or near the
25 fastener, and (ii) contact sensed with a surface at or near the distal end of the fastener body.

Another aspect of the invention provides a fastener sized and configured for deployment in tissue. The fastener includes a fastener body having a distal end
30 for penetrating tissue in response to a force. The fastener body also has a proximal end for releasably coupling the fastener body to a force applier. The fastener includes a stop structure associated with the proximal end to prevent over-penetration of the fastener
35 body into tissue. In one embodiment, the stop structure

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couples the fastener body to the force applier, e.g., by a magnetic or mechanical coupling. On one embodiment, the fastener body can comprise, e.g., a helical coil.

Another aspect of the invention provides a
5 fastener sized and configured for deployment in tissue: The fastener comprises a fastener body having a distal end for penetrating tissue in response to a force. The fastener body also has a proximal end for releasably coupling the fastener body to a force applier. A tracking
10 wire is coupled to the proximal end to guide the force applier into operative contact with the fastener.

Another aspect of the invention provides a prosthesis comprising a prosthesis body and a fastener assembly integrally carried by the prosthesis body. The
15 fastener assembly includes at least one fastener deployable into tissue in response to force applied by a force applier. A tracking wire is coupled to the fastener to guide the force applier into operative contact with the fastener.

Another aspect of the invention provides a prosthesis comprising a prosthesis body and a fastener assembly integrally carried by the prosthesis body. The assembly includes at least one fastener deployable into
20 tissue in response to non-rotational force applied by a force applier.
25

Brief Description of the Drawings

The invention will be understood from the following detailed description of preferred embodiments, taken in conjunction with the accompanying drawings,
30 wherein:

Fig. 1 is a perspective view of one embodiment of an endovascular graft delivery device shown positioned within an abdominal aortic aneurysm;

Fig. 2 is a perspective view of one embodiment
35 the deployment of an endovascular graft within the

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aneurysm of Fig. 1;

Fig. 3 is a perspective view of a fully deployed straight endovascular graft of Fig. 2;

Fig. 4 is a perspective view of a fully
5 deployed bifurcated endovascular graft broken away to show an anchoring scaffold at one end;

Fig. 5 is a perspective view similar to Fig. 5 showing an alternative scaffold structure;

Fig. 6 is a perspective view showing one
10 embodiment of a device for directing the fastener applier;

Fig. 7 is a perspective view showing the device of Fig. 6 upon insertion within the deployed endovascular graft of Fig. 3 with both the graft and
15 scaffolding broken away;

Fig. 8 is a perspective view of the device of Fig. 6 showing activation of one embodiment of a stabilizing device attached to the directing device;

Fig. 9 is a perspective view of the control
20 assembly in Fig. 8 articulating the directing device of Fig. 6;

Fig. 10 is a perspective view of an alternative embodiment of the stabilization device of Fig. 8;

25 Fig. 11 is a perspective view showing the activation of the alternative stabilization device of Fig. 10;

Fig. 12 is a perspective view showing another embodiment of the stabilization device of Fig. 8;

30 Fig. 13 is a perspective view showing activation of the stabilization device of Fig. 12;

Fig. 14 is one embodiment of the fastener applier;

35 Fig. 14A is an enlarged view of the distal end of the fastener applier shown in Fig. 14, showing the

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details of the fastener drive mechanism;

Fig. 14B is a section view of the interior of the handle of the fastener applier shown in Fig. 14;

Fig. 15 is a perspective view of the fastener
5 applier of Fig. 14 being positioned within directing device of Fig. 6;

Fig. 16 is an enlarged cross-sectional view of one embodiment of the fastener applier of Fig. 14;

Fig. 17 is an enlarged cross-sectional view of
10 the attachment applier showing one embodiment of the proximal end of the helical fastener and the drive mechanism;

Fig. 18 is a enlarged perspective view of one embodiment of the helical fastener of Fig. 16;

Fig. 19 is an enlarged view of the attachment
15 applier showing one embodiment of the control assembly that activates the fastener applier;

Fig. 20 is an enlarged view of the attachment
20 applied activated with a fastener implanted into the graft and vessel wall;

Fig. 21 is an enlarged view of the completed attachment of the proximal graft of Fig. 3 to the vessel wall with fasteners;

Fig. 22 is a perspective view of the graft of
25 Fig. 4 completely attached to the vessel;

Fig. 23 is an enlarged section view of the drive mechanism of the fastener applier shown in Fig. 14, showing a contact/force sensing assembly that disables the applier in the absence of desired contact between the
30 fastener and a targeted tissue region;

Fig. 24 is an enlarged section view of the drive mechanism of the fastener applier shown in Fig. 14, showing the contact/force sensing assembly enabling use of the applier in response to desired contact between the
35 fastener and the targeted tissue region;

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Figs. 25A and 25B are enlarged views of the distal end of a fastener applier showing the details of an alternative embodiment of the fastener drive mechanism;

5 Fig. 26A is an enlarged section view of the drive mechanism of the fastener applier shown in Figs. 25A and 25B showing a contact/force sensing assembly that disables the applier in the absence of desired contact between the fastener and a targeted tissue region;

10 Figs. 26B and 26C are enlarged section views of the drive mechanism of the fastener applier shown in Figs. 25A and 25B, showing the contact/force sensing assembly enabling use of the applier in response to desired contact between the fastener and the targeted
15 tissue region;

 Fig. 27 is a perspective view of a helical fastener that can be used in association with the fastener applier shown in Figs. 14, 23, and 24;

 Fig. 28A is a perspective view of a helical
20 fastener that can be used in association with the fastener applier shown in Figs. 25A and 25B;

 Fig. 28B is perspective view of a helical fastener that can be used in association with the fastener applier shown in Figs. 26A to 26C;

25 Fig. 29 is an enlarged side view, partially in section, of a fastener applier having an angled applicator end that can be used to deploy the helical fastener shown in Fig. 27 without use of a separate directing device;

30 Fig. 30 is an enlarged side view, partially in section, of an alternative embodiment of an angled fastener applier that can be used to deploy the helical fastener shown in Fig. 27 without use of a separate directing device;

35 Fig. 31 is an enlarged side view, partially in

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section, of an alternative embodiment of an angled fastener applier that can be used to deploy the helical fastener shown in Fig. 27 without use of a separate directing device, the fastener applier having an articulating applicator end;

Fig. 32 is a perspective view of an endovascular prosthesis shown positioned within an abdominal aortic aneurysm, the prosthesis including an integrated fastener assembly;

Fig. 33 is a perspective view of the endovascular prosthesis shown in Fig. 32, with an intraluminal tool deployed to operatively interact with the integrated fastener assembly, to temporarily or permanently anchor the prosthesis to the wall of the vessel;

Fig. 34 is a side view of a fastener that forms a part of the integrated fastener assembly shown in Fig. 33, the fastener having a stem, which is shown in a normally spread-apart condition before its association with the integrated fastener assembly;

Fig. 35 is a side view of the fastener shown in Fig. 34, the fastener stem now being shown in a closed condition and housed within a grommet that forms a part of the integrated fastener assembly;

Figs. 36 and 37 are side views showing the use of the intraluminal tool shown in Fig. 33 to apply force to drive the fastener from its position shown in Fig. 35 and through the vessel wall;

Fig. 38 is the integrated fastener assembly after deployment to anchor a prosthesis to a vessel wall;

Fig. 39 is a side view showing the use of a tracking wire to guide a intraluminal tool into contact with a fastener, so that force can be applied to drive the fastener through the vessel wall;

Fig. 40 is an embodiment of a prosthesis

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delivery catheter for a prostheses in which the stent structure covers only a portion of the prosthesis, the catheter including an array of stabilization struts to help hold the prosthesis in position against the flow of blood;

Fig. 41 is another embodiment of a prosthesis delivery catheter for a prostheses in which the stent structure covers only a portion of the prosthesis, the catheter including an array of inverted stabilization struts to help hold the prosthesis in position against the flow of blood; and

Fig. 42 is another embodiment of a prosthesis delivery catheter for a prostheses in which the stent structure covers only a portion of the prosthesis, the catheter including a stabilization basket to help hold the prosthesis in position against the flow of blood.

Detailed Description of the Invention

I. Delivering a Prosthesis

Fig. 1 depicts an endovascular graft delivery catheter 10 as it is being positioned over a guidewire 12 in a body lumen. The catheter 10 carries a prosthesis 14 (see Fig. 2), which is placed at a targeted site, e.g., by radial expansion of the prosthesis 14 (see Fig. 3). After expansion of the prosthesis 14, one or more fasteners 28 (see Figs. 15 and 16) are introduced by a fastener attachment assembly to anchor the prosthesis 14 in place.

For the purposes of illustration, Fig. 1 shows the targeted site as being within an abdominal aortic aneurysm 11. The targeted site can be elsewhere in the body. In the illustrated arrangement, the prosthesis 14 takes the form of an endovascular graft.

Fig. 2 depicts the initial stage of graft deployment at the targeted site. While the deployment method can

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vary, in the illustrated embodiment, the delivery catheter 10 has a movable cover 13, which overlays the graft 14. When the cover 13 is pulled proximally, the graft 14 is free to radially expand, thereby enlarging to
5 contact the internal walls of the blood vessel. The graft 14 is shown to be self-expanding. Alternatively, the graft 14 can utilize an expanding member, such as a balloon or mechanical expander.

The process of graft deployment is continued, until
10 the graft 14 is fully deployed within the vessel. The graft 14 can be sized and configured to be either straight or bifurcated form. Fig. 3 depicts a completely deployed straight graft 14. Fig. 4 depicts a completely deployed bifurcated graft 15.

15 **A. The Prosthesis**

The graft 14 desirably incorporates a support frame or scaffold 16. The scaffold 16 may be elastic, e.g., comprised of a shape memory alloy elastic stainless steel, or the like. For elastic scaffolds, expanding
20 typically comprises releasing the scaffolding from a constraint to permit the scaffold to self-expand at the implantation site. In the illustrated arrangement, the cover 13 serves as a radial constraint. Alternatively, placement of a tubular catheter, delivery sheath, or the
25 like over the scaffold 16 can serve to maintain the scaffold in a radially reduced configuration. In this arrangement, self-expansion of the scaffold 16 is achieved by pulling back on the radial constraining member, to permit the scaffold 16 to assume its larger
30 diameter configuration.

Alternatively, the scaffold 16 may be constrained in an axially elongated configuration, e.g., by attaching either end of the scaffold to an internal tube, rod, catheter or the like. This maintains the scaffold 16 in
35 the elongated, reduced diameter configuration. The

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scaffold 16 may then be released from such axial constraint in order to permit self-expansion.

Alternatively, the scaffold 16 may be formed from a malleable material, such as malleable stainless steel of other metals. Expansion may then comprise applying a radially expansive force within the scaffold to cause expansion, e.g., inflating a scaffold delivery catheter within the scaffold in order to affect the expansion. In this arrangement, the positioning and deployment of the endograft can be accomplished by the use of an expansion means either separate or incorporated into the deployment catheter. This will allow the endograft to be positioned within the vessel and partially deployed while checking relative position within the vessel. The expansion can be accomplished either via a balloon or mechanical expansion device. Additionally, this expansion stabilizes the position of the endograft within the artery by resisting the force of blood on the endograft until the endograft can be fully deployed.

The graft 14 may have a wide variety of conventional configurations. It can typically comprise a fabric or some other blood semi-impermeable flexible barrier which is supported by the scaffold 16, which can take the form of a stent structure. The stent structure can have any conventional stent configuration, such as zigzag, serpentine, expanding diamond, or combinations thereof. The stent structure may extend the entire length of the graft, and in some instances can be longer than the fabric components of the graft. Alternatively, the stent structure can cover only a small portion of the prosthesis, e.g., being present at the ends. The stent structure may have three or more ends when it is configured to treat bifurcated vascular regions, such as the treatment of abdominal aortic aneurysms, when the stent graft extends into the iliac arteries. In certain

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instances, the stent structures can be spaced apart along the entire length, or at least a major portion of the entire length, of the stent-graft, where individual stent structures are not connected to each other directly, but
5 rather connected to the fabric or other flexible component of the graft.

One illustrative embodiment of the graft scaffold 16 or stent structure is illustrated in the area broke away in Fig. 4. Here, the stent structure is in the form of a
10 simple zigzag pattern, however it is contemplated that the stent design could involve more complex patterns 17 as depicted in Fig. 5. Although only one stent structure within the graft is depicted, in Fig. 4 and 5, it is contemplated that multiple independent stent structures
15 could be incorporated into the graft, as previously described.

Fig. 40 shows an embodiment of a prosthesis delivery catheter 600 for a prostheses 14 in which the stent structure 16 covers only a portion of the prosthesis, e.g., being present only at the ends. As shown in Fig.
20 40, the prosthesis delivery catheter 600 (which is shown deployed over a guidewire 610) includes an array of stabilization struts 612 that are releasably coupled to the stent structure 16 at the end of the prosthesis 14, e.g., by sutures that can be released by pulling on a
25 drawstring (not shown) that passes through a lumen in the catheter 600. The stabilization struts 612 hold the self-expanding stent structure 16 in position against the vessel wall 34, while the remainder of the prosthesis 14 is being deployed (by withdrawal of a delivery sheath
30 614). The struts 612 support the stent structure 16 (and thus the overall prosthesis 14) against the force of blood flow through the vessel during prosthesis deployment. The catheter 600 can also include a nose
35 cone 618 at its distal end to diffuse blood flow toward

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the vessel wall, to aid in supporting the prosthesis 14 during its deployment. Upon, deployment of the prosthesis 14, the struts 612 can be detached from the stent structure 14 by pulling upon the drawstring to release the sutures, and the catheter 600 is withdrawn over the guidewire 610 through the delivery sheath 614 (the struts 612, freed from the stent structure 16, fold back upon the catheter 600 during passage through the delivery sheath 614).

10 Fig. 41 shows an alternative embodiment of a prosthesis delivery catheter 700 for a prostheses 14 in which the stent structure 16 covers only a portion of the prosthesis, e.g., being present at the ends. As shown in Fig. 40, the prosthesis delivery catheter 700 (which is
15 also shown deployed over a guidewire 710) includes an array of inverted stabilization struts 712 that are releasably coupled to the stent structure 16 at the end of the prosthesis 14, e.g., by sutures that can be released by pulling on a drawstring (not shown) that
20 passes through a lumen in the catheter 700. The inverted stabilization struts 712, like the struts 612 shown in Fig. 40, hold the self-expanding stent structure 16 in position against the vessel wall 34, while the remainder of the prosthesis 14 is being deployed (by withdrawal of
25 a delivery sheath 714). Like the catheter 600 in Fig. 40, the catheter 700 can also include a nose cone 718 at its distal end to diffuse blood flow toward the vessel wall. Upon, deployment of the prosthesis 14, the struts 712 are detached from the stent structure 14 by pulling upon the
30 drawstring not shown), and the catheter 700 is withdrawn over the guidewire 710 through the delivery sheath 714 (the struts 612, freed from the stent structure 16, fold back upon the catheter 600 during passage through the delivery sheath 614).

35 Fig. 42 shows another alternative embodiment of a

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prosthesis delivery catheter 800 for a prostheses 14 in which the stent structure 16 covers only a portion of the prosthesis, e.g., being present at the ends. As shown in Fig. 42, the prosthesis delivery catheter 800 (which is
5 also shown deployed over a guidewire 810) includes a self-expanding stabilization basket 812. The stabilization basket 812 holds the self-expanding stent structure 16 in position against the vessel wall, while the remainder of the prosthesis 14 is being deployed (by
10 withdrawal of a delivery sheath 814). Like the catheters 600 and 700 in Figs. 40 and 41, the catheter 800 can also include a nose cone 818 at its distal end to diffuse blood flow toward the vessel wall. Upon, deployment of the prosthesis 14, the stabilization basket is placed
15 into a collapsed condition by withdrawal through the delivery sheath 814, as the catheter 800 is withdrawn over the guidewire 810.

In all of the just-described embodiments, the guidewire 610, 710, 810 can be subsequently used to
20 deploy a fastener attachment assembly for the prosthesis 14, as will be described in greater detail next.

II. Fastening the Prosthesis

In a desired embodiment, a fastener attachment assembly is provided that makes possible intraluminal
25 fastener attachment. The attachment assembly can be variously constructed.

A. Two Component Fastener Guide and Attachment Assembly

In one arrangement, the fastener attachment assembly
30 comprises a fastener guide or directing component 18 and a fastener applier component 27. The guide component 18 desirably has a steerable or deflectable distal tip, which is initially deployed over the guidewire 12. In use, the guidewire 12 that is used to deliver and

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position the prosthesis 14 desirably remains within the vessel for subsequent deployment of the fastener guide component 18.

5 Optionally, the guide component 18 includes a stabilizer for holding, following removal of the guidewire 12, the deflected tip against a location in the prosthesis 14, to which a fastener 28 for the prosthesis 14 is to be applied.

10 In this arrangement, the applier component 27 is desirably deployed through the guide component 18. The fastener applier 27 carries at least one fastener 28 and a fastener drive mechanism 100 for advancing the fastener 28, so that it penetrates the prosthesis 14 and underlying vessel wall, to thereby anchor the prosthesis 15 14 firmly in place.

1. Fastener Directing Component

Fig. 6 depicts one embodiment of the directing or guide component 18 that forms a part of the fastener attachment assembly. The component 18 takes the form of a directing device 18. The device 18 has an obturator 19 20 positioned within a lumen of the directing device 18, which extends past the distal of the tip of the directing device. The obturator 19 has a lumen to allow for delivery of the directing device 18 over the guidewire 25 12, as shown in Fig. 7.

The directing device 18 desirably includes an integrated stabilizing device 20, which aids in maintaining position of the directing device 18 within the vessel upon removal of the guidewire 12. In one 30 embodiment, the stabilizing device 20 is spring-loaded and is positioned for deployment when the obturator 19 and guidewire 12 are removed (see Fig. 8).

In the illustrated embodiment (see Fig. 8), the directing device 18 includes a control assembly 21. In 35 one embodiment the control assembly 21 features a movable

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wheel or lever 22, which operate interior steering wires in a conventional fashion to deflect the distal tip 23 of the directing device 18 toward a desired location, as seen in Fig. 9. It is contemplated that the control assembly for the directing device 18 could be activated mechanically, electrically, hydraulically or pneumatically. The control assembly 21 has a through lumen to allow for the passage of the obturator 19 and applier component 27.

Fig. 10 depicts an alternative embodiment, in which the stabilizing device 20 takes the form of a movable strut assembly 24. The movable strut assembly 24 can be activated, e.g., through a lever 25 on the control assembly (see Fig. 11). In both embodiments (Fig. 7 and 10) the stabilizing device 20 is distal to the end of the directing device.

In another alternative embodiment (see Fig. 12), the stabilizing device 20 takes the form of an expandable member 26 adjacent to the distal tip of the directing device. As shown in Fig. 13, the expandable member 26 can be activated, e.g., through a lever 25 on the control assembly 21. However it also contemplated that this type of stabilizing device 20 could also be inflatable. In all embodiments the stabilizing device could be use to stabilize the directing device 18 either concentrically or eccentrically within the vessel.

In another embodiment, a separate stabilization device could be used in cooperation with the directing device 18 and to access the vessel. This separate stabilization device could incorporate the forms of the stabilizing devices described above, or some other form of stabilization mechanism.

2. Fastener Applier Component

Fig. 14 shows one embodiment of the applier component 27 that forms a part of the fastener attachment

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assembly. The component 27 takes the form of a fastener applicer 27. Fig. 15 depicts the fastener applicer 27 being deployed through a lumen of the directing device 18 to the site where a fastener 28 will be installed.

5 Located at the distal end of the fastener applicer 27 (see Fig. 14) is a fastener drive mechanism 100. In the illustrated embodiment (see Fig. 14A), the drive mechanism 100 includes a driver 29 that is coupled to a carrier 102. The coupling between the driver 29 and
10 carrier 102 can take different forms - e.g., magnets, graspers, or other suitable mechanical connection. In the embodiment illustrated in Fig. 14A, the driver 29 and carrier 102 are integrally connected as a single unit.

 The carrier 102 is sized and configured to engage a
15 selected fastener 28. In Fig. 14A, the fastener takes the form of a helical fastener of the type shown in Figs. 18 and 27. As best shown in Fig. 27, and as will be described in greater detail later, the helical fastener 28 in Fig. 26 is an open coil 148 with a sharpened
20 leading tip 142. The proximal end 144 of the fastener 28 includes an L-shaped leg 146. The L-shaped leg 146 desirably bisects the entire interior diameter of the coil 148; that is, the L-shaped leg 146 extends completely across the interior diameter of the coil 148,
25 as Fig. 27 shows. The L-shaped leg 146 serves to engage the carrier 102 of the fastener applicer 27, which rotates the helical fastener to achieve implantation. The L-shaped leg 146 also serves as a stop to prevent the helical fastener from penetrating too far into the
30 tissue.

 The carrier 102 in Fig. 14A includes a slot 180, which receives the L-shaped leg 146 to couple the fastener 28 for rotation with the carrier 102. The turns of the coil 148 rest in complementary internal grooves 32
35 that surround the carrier 102. The grooves 32 could be

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positioned along the entire length of the fastener 28 or within a portion of its length.

The actuation of the drive mechanism 100 can, of course, be accomplished in various ways, e.g., mechanical (i.e., manual or hand-powered), electrical, hydraulic, or pneumatic. In the illustrated embodiment (see Fig. 14B), a drive cable 30 couples the fastener driver 29 to an electric motor 106 carried in the applier handle 108. The drive cable 30 is desirably made of a suitable material that allows for both bending and rotation. Driven by the motor 106 (which is, in turn, under the control of motor control unit 31, as will be described later), the drive cable 30 rotates the driver 29 and, with it, the carrier 102. The carrier 102 imparts rotation and torque to the helical fastener 28 for implantation in tissue.

Fig. 16 is an enlarged cross-sectional view of fastener applier 27 and directing device 18. Fig. 17 is an enlarged cross-sectional view of the fastener applier 27 with a cross-section of the fastener driver 29 depicting the engagement between the fastener driver 29 and helical fastener 28. Fig. 19 depicts the fastener applier 27 during activation of the fastener drive mechanism 100. Activation of the drive mechanism 100 rotates, as a unit, the drive shaft 30, the driver 29, the carrier 102, and helical fastener 28. This rotation causes the helical fastener 28 to travel within the internal grooves 32 of the fastener applier and into the prosthesis 14 and vessel wall 34 (see Fig. 20). Fig. 21 illustrates a completed helical fastener 28 attachment of the graft 14 to the vessel wall 34.

In use, the applier 27 is advanced through the directing device 18 and into contact with the prosthesis. The operator actuates the control unit 31 by contacting a control switch 110 (see Figs. 14 and 14B). This action causes the helical fastener 28 to be rotated off the

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carrier 102 and through the prosthesis 14 and into the vessel wall 34. The motor control unit 31 desirably rotates the drive cable 30 a specific number of revolutions with each activation command. This can be
5 accomplished by incorporating a mechanical or electrical counter.

With the deployment of a fastener 28, the applier 27 is retrieved through the directing device 18, and another fastener 28 is loaded into the carrier 102. The
10 directing device 18 is repositioned and stabilized, and the applier 27 is advanced again through the directing device 18 and into contact with the prosthesis 14. The operator again actuates the control unit 31 by contacting the control switch 110 to deploy another fastener 28.
15 This process is repeated at both proximal and/or distal ends of the prosthesis 14 until the prosthesis 14 is suitably attached and sealed to the vessel wall 34. It is contemplated that from about two to about twelve fasteners 28 may be applied at each end of the prosthesis
20 14 to affect anchorage. The fasteners 28 can be applied in a single circumferentially space-apart row, or may be applied in more than one row with individual fasteners being axially aligned or circumferentially staggered.

Fig. 22 illustrates a perspective view of a graft
25 prosthesis attached to the vessel wall both proximally and distally. It is contemplated that the present invention can be used for graft attachment of both straight and bifurcated grafts within the aorta and other branch vessels.

30 An alternative embodiment of the drive mechanism 100 is shown in Figs. 25A and 25B. In this embodiment, the driver 29 is coupled to a carrier 150, which forms a part of the helical fastener 28 itself, as also shown in Fig. 28A. As shown in Fig. 28A, the helical fastener 28 is,
35 like the fastener shown in Fig. 27, an open coil 148 with

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a sharpened leading tip 142. The proximal end 144 of the fastener 28 includes the carrier 150.

The carrier 150 includes a slot 182. The slot 182 engages a drive flange 184 on the driver 29 (see Fig. 25A) to impart rotation of the driver 29 to rotation of the helical fastener 28 during the implantation process. Like the L-shaped leg of the fastener shown in Fig. 27, the carrier 150 also serves as a stop to prevent the helical fastener from penetrating too far into the tissue.

The coupling engagement between the carrier 150 and the driver 29 could be accomplished in various ways, e.g., by separate graspers or grippers, a magnetic couple, or any other suitable mechanical connecting means. In the illustrated embodiment, the driver 29 is made of a magnetized material, and the carrier 150 is made from a material that is magnetically attracted toward the magnetized material. Of course, a reverse arrangement of magnetized and magnetically attracted materials could be used.

In this arrangement, the motor coupling 132 between the drive cable 30 and the motor 106 accommodates axial displacement of the motor cable 30 (left and right in Figs. 25A and 25B) without interrupting the drive connection with the motor 106. With the distal tip of the applier device 27 in contact with the prosthesis 14 (see Fig. 25A), the operator actuates the control unit 31 by contacting a control switch 110. The control unit 31 commands the motor 106 to rotate the drive cable 30 to impart rotation to the driver 29 and the magnetically attached helical fastener 28. This action causes the magnetically attached helical fastener 28 to be rotated into prosthesis 14 and the vessel wall 34 (see Fig. 25B). Due to the magnetic coupling, as the fastener 28 is deployed to the left in Fig. 25B, the driver 29 moves in

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tandem with carrier 150 (also to the left in Fig. 25B). Due to the magnetic coupling between the carrier 150 and the driver 29, the operator must exert a deliberate separation force to decouple the carrier 150 (and, with
5 it, the fastener 28) from the driver 29. This arrangement prevents inadvertent release of a fastener 28.

As before described, with the deployment of a fastener 28, the applier 27 is retrieved through the directing device 18, and another fastener 28 is
10 magnetically coupled to the driver 29. The directing device 18 is repositioned and stabilized, and the applier 27 is advanced again through the directing device 18 and into contact with the prosthesis 14. The operator again actuates the control unit 31 by contacting a control
15 switch 110 to deploy another fastener 28. This process is repeated at both proximal and/or distal ends of the prosthesis 14 until the prosthesis 14 is suitably attached and sealed to the vessel wall 34.

As indicated in the above description, the outer
20 diameter of the applier component 27 is desirably sized and configured to pass through the lumen of the directing component 18, which can take the form of a suitable steerable guide catheter, to direct the applier component 27 to the desired location. As also above described, the
25 applier component 27 is desirably configured to implant one fastener 28 at a time (a so-called "single fire" approach). This is believed desirable, because it reduces the complexity of the design and accommodates access of the applier 27 through tortuous anatomy. Fastener
30 appliers 27 which carry a single fastener can have a lower profile and may be more effective and less traumatic than fastener appliers which carry multiple fasteners. Still, in alternative embodiments, the applier component 27 may, if desired, be configured to carry
35 multiple fasteners. Moreover, the fastener applier 27

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may simultaneously deploy multiple fasteners in the preferred circumferentially spaced-apart space pattern described above.

a. Prosthesis/Tissue Contact Sensing

5 The fastener applier 27 desirably incorporates a function that prevents actuation of the motor 106 until the tip of the applier 27 is in a desired degree of contact with the prosthesis or tissue surface. This prevents inadvertent discharge of a fastener 28 and/or
10 separation of the fastener 28. This function can be implemented, e.g., using a contact or force sensor, which is either mechanical or electrical in design.

When the fastener applier 27 is of the type shown in Figs. 14A, 14B, and 14C (see Figs. 23 and 24), the
15 contact or force sensing function can, e.g., utilize the distal tip 120 of the carrier 102 to transmit a contact force. This force can be transmitted to a force or contact sensing switch 122 located, e.g., within the fastener applier handle 108. In this arrangement, the
20 switch 122 can be part of the electrical circuit between the actuator switch 110 and the control unit 31.

In the illustrated embodiment, the switch 122 includes a stationary switch element 128 (coupled to the interior of the handle 108) and a movable switch element
25 130 (carried by the drive cable 31). In this arrangement, the motor coupling 132 between the drive cable 30 and the motor 106 accommodates axial displacement of the motor cable 30 (left and right in Figs. 23 and 24) without interrupting the drive connection with the motor 106. The
30 drive cable 30 is coupled by a bearing 134 to the movable switch element 130, so that the switch element 130 moves in response to movement of the drive cable 30. The stationary switch element 128 is not coupled to the movable drive cable 30, which slidably passes through the
35 switch element 130.

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Due to this arrangement, axial displacement of the drive cable 30 moves the switch element 130 relative to the switch element 128. More particularly, displacement of the drive cable 30 to the left in Fig. 23 moves the switch element 130 to the left, away from the switch element 128. Conversely, displacement of the drive cable 30 to the right in Fig. 23 moves the switch element 130 to the right, toward the switch element 128.

A spring 126 normally biases the switch elements 128 and 130 apart, comprising an electrically opened condition. In this condition, operation of the actuating switch 110 does not serve to actuate the control unit 31, as the electrically open switch 122 interrupts conveyance of the actuation signal to the motor control unit 31. When the switch elements 128 and 130 are in the electrically opened condition, the drive cable 30 is displaced to the left to position the carrier tip 120 beyond the distal tip 124 of the fastener applier 27. The carrier tip 120 therefore makes contact with the prosthesis 14 or tissue in advance of the applier tip 124.

When the carrier tip 120 contacts the surface of the prosthesis or tissue with sufficient force to compress the spring 126, the drive cable 30 is displaced against the biasing force of the spring to the right in Fig. 23.

This moves the switch element 130 to the right. Ultimately, contact between the switch elements 128 and 130 will occur, as shown in Fig. 24. The contact establishes an electrically closed condition. In this condition, operation of the actuating switch 110 serves to actuate the control unit 31. As shown in Figs. 23 and 24, a contact screw 136 can be provided to adjust the amount of displacement required to close the switch elements 128 and 130.

Upon removal of contact force, or in the absence of

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sufficient contact force, the spring 126 urges the switch elements 128 and 130 toward the electrically opened condition. The distal tip of the carrier 102 is located distally beyond the distal tip of the applier 27.

5 It should be appreciated that the translation of movement of the carrier tip 120 to the switch 122 need not occur along the entire length of the drive cable 30. For example, the switch 122 can be located in a translation space between the carrier 102 and the driver
10 29. In this arrangement, the driver 29, coupled to the drive cable 30 need not accommodate axial displacement. Instead, relative movement of the carrier 102 toward the driver 29 in response to contact with the prosthesis 14 will mechanically couple the carrier 10 with the driver
15 29 (e.g., through a slot and flange connection similar to that shown in Figs. 25A and 25B), while also closing the switch 122 to energize the circuit between the actuator switch 110 and the motor control unit 31.

 When the fastener applier 27 is of the type shown in
20 Fig. 25A and 25B (see Figs. 26A, 26B, and 26C), the contact or force sensing function can, e.g., utilize a force sensing rod 190 that slidably passes through a central passage 192 in the carrier 150' (the carrier 150' is shown in Fig. 28B), the driver 29 and the drive cable
25 30. The rod 190 is coupled to the movable switch element 130. In this embodiment, the switch element 130 translates left and right over the drive cable 30, which rotates on a bearing 134 within the switch element 130.

 As in the preceding embodiment, the spring 126
30 normally biases the switch elements 128 and 130 apart, comprising an electrically opened condition. When the switch elements 128 and 130 are in the electrically opened condition, the force sensing rod 190 is displaced to the left beyond the distal tip 124 of the fastener
35 applier 27. The force sensing rod 190 therefore makes

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contact with the prosthesis 14 or scaffold structure 16 in advance of the applier tip 124.

When the rod 190 contacts the surface of the prosthesis or scaffold structure with sufficient force to compress the spring 126, the rod 190 is displaced against the biasing force of the spring 126 to the right in Fig. 26A. This moves the switch element 130 to the right. Ultimately, contact between the switch elements 128 and 130 will occur, as shown in Fig. 26B. The contact establishes an electrically closed condition. In this condition, operation of the actuating switch 110 serves to actuate the control unit 31. This action causes the helical fastener 28 to be rotated into the scaffold structure 16 and into the vessel wall 34 (see Fig. 26C). Due to the magnetic coupling between the driver 29 and carrier 150', the driver 29 is moved in tandem with attached carrier 150' to the left in Fig. 26B, as the fastener 28 is deployed. Also, due to the magnetic coupling between the carrier 150 and the driver 29, the operator must exert a separation force to decouple the carrier 150 (and, with it, the fastener 28) from the driver 29. As before described, this arrangement prevents inadvertent release of a fastener 28. A contact screw 136 can be provided to adjust the amount of displacement required to close the switch elements 128 and 130.

Upon removal of contact force, or in the absence of sufficient contact force, the spring 126 urges the switch elements 128 and 130 toward the electrically opened condition, moving the tip of the rod 190 out beyond the distal tip 124 of the applier 27.

The contact or force sensing arrangements just described can also generate an audible and/or visual output to the operator, to indicate that sufficient contact force between the applier device 27 and the prosthesis or tissue exists.

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B. Angled Component Fastener Guide and Attachment Assembly

In another arrangement (see Fig. 29), the fastener attachment assembly comprises a unitary, angled fastener guide and applier component 160. In this arrangement, the component 160 includes a fastener drive mechanism 162 that places the carrier 164 holding the fastener 28 in a perpendicular or near perpendicular position with respect to the prosthesis or tissue. This configuration eliminates the need for a separate steerable guide component 18 for the fastener component 27, previously described.

The drive mechanism 162 can vary. In the illustrated embodiment (shown in Fig. 29), the mechanism 162 includes a beveled drive gear 168 coupled to the drive cable 30. The drive gear 168 operatively meshes with a transfer or pinion gear 170, which is coupled to the carrier 164. The axes of rotation of the drive gear 168 and pinion gear 170 are offset about ninety degrees, so that rotation of the drive cable 30 along the axis of the vessel is translated into rotation of the carrier 164 generally perpendicular to the wall of the vessel. The fastener guide and applier component 160 can be positioned and stabilized within the vessel in various ways, e.g., through the use external spring loaded strut or the like (as shown in association with the directing component 18 discussed above), or by use of an expandable member 166 (as Fig. 29 shows). The expansion member 166 can comprise either a balloon or mechanical expansion device. The expansion member 166 stabilizes the position of both the prosthesis and the fastener guide and applier component 160 within the vessel by resisting the force of blood until the prosthesis can be anchored.

As Fig. 30 shows, the fastener guide and applier

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component 160 can, if desired, provide an angled deployment between the drive cable 30 and carrier 164 that is somewhat less than ninety-degrees, to aid in intraluminal manipulation of the carrier into perpendicular contact position against the wall of the vessel. As Fig. 31 shows, the fastener guide and applicator component 160 can, if desired, be articulated between the drive cable 30 and carrier 164. In this arrangement, a remote control mechanism is desirable provided to move the carrier 164 from a first, generally straight position (shown in phantom lines in Fig. 31) for deployment to the targeted site, to a second, articulated position (shown in solid lines in Fig. 31) for alignment of the carrier 164 in contact against the vessel wall.

15 III. The Fasteners

As illustrated and described thus far, introduction of the fasteners 28 will typically be affected after the prosthesis 14 has been initially placed. That is, initial placement of the prosthesis 14 will be achieved by self-expansion or balloon expansion, after which the prosthesis 14 is secured or anchored in place by the introduction of a plurality of individual fasteners. The fasteners 28 may be placed only through the fabric of the prosthesis 14, i.e., avoiding the scaffold structure. Alternately, the fasteners 28 can be introduced into and through portions of the scaffold structure itself. The prosthesis 14 may include preformed receptacles, apertures, or grommets, which are specially configured to receive the fasteners. The fasteners 28 may be introduced both through the fabric and through the scaffold structure. The fasteners can be introduced singly, i.e., one at a time, in a circumferentially spaced-apart pattern over an interior wall of the prosthesis 14.

In the exemplary embodiment, the fasteners 28 are helical fasteners, so that they can be rotated and

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"screwed into" the prosthesis 14 and vessel wall. A desired configuration for the helical fastener 28 (see Figs. 27, 28A, and 28B) is an open coil 148, much like a coil spring. This configuration allows the fastener 28 to capture a large area of tissue, which results in significantly greater holding force than conventional staples, without applying tissue compression, which can lead to tissue necrosis.

As Figs. 27, 28A, and 28B show, the leading tip 142 of the helical fastener 28 is desirable sharp to allow it to penetrate through the artery wall and/or calcified tissue. This distal tip 142 can be sharpened to cut a helical path through the tissue or it can be sharpened to a point to penetrate the tissue without cutting.

The proximal end 144 of the fastener serves two design functions. The first function is to engage the carrier 102 of the fastener applier 27, which rotates the helical fastener during the implantation process. The second function is to act as a stop to prevent the helical fastener from penetrating too far into the tissue.

In one embodiment (see Fig. 27), the proximal end 144 of the helical fastener 28 includes an L-shaped leg 146 of the coil 148 bisecting the fastener diameter. The leg 146 of the coil 148 comes completely across the diameter to prevent the fastener from being an open coil and to control the depth of penetration into the tissue. In addition, the leg 146 of the coil 148 can be attached to a previous coil to strengthen the entire structure and provide a more stable drive attachment point for the fastener applier. This attachment could be achieved via welding, adhesive or any other suitable means.

Alternatively (as shown in Figs. 28A and 28B), the proximal end 144 of the fastener 28 could incorporate a separate cap or carrier 150 or 150' that serves the same

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function as the leg 146 of the coil 148 in Fig. 27. The carrier 150 or 150' could feature several methods to attach to the fastener applier drive mechanism 100. These include separate graspers or grippers, a magnetic couple
5 (as previously described), or any other suitable mechanical connecting means. In Figs. 28A and 28B, the carrier 150 and 150' includes a slot 180 and 182' to mate with a drive flange (as previously described). As also previously described, a magnetic coupling is implemented
10 between the carrier 150 and 150' and the corresponding drive member, to prevent inadvertent separation during use.

In Fig. 28B, the carrier 150' also includes a passage 152 for holding the contact/force sensing rod 190
15 shown in Figs. 26A, 26B, and 26C.

The fasteners 28 shown in Figs. 27, 28A, and 28B can be made from stainless steel or other types of implantable metal, however it is also envisioned that the fasteners in the above descriptions could be made from
20 implantable polymers or from a biodegradable polymer or combinations of all materials thereof. Desirably, a fastener 28 will have between 2 and 10 turns and will be between 1 mm and 10 mm long. The space between the individual coils will be between .25 mm and 3 mm. The
25 diameter of the fastener 28 will be between 1 mm and 6 mm.

IV. Prosthesis with Integrated Fastener Assembly

Fig. 32 shows a prosthesis 500 that includes at least one integrated fastener assembly 502. Fig. 32
30 shows the prosthesis 500 deployed in a targeted intraluminal region, in particular, within an abdominal aortic aneurysm 504. The prosthesis 500 can be deployed elsewhere in the body.

The prosthesis 500 desirably includes a fabric
35 material or the like carried by a support frame or

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scaffold 504, as previously described. The scaffold 504 can be made, e.g., from an elastic material that self-expands radially during deployment from a sheath, or from a malleable material that expands radially in response to
5 a radially expansive force applied within the scaffold by a balloon or a mechanical expansion device.

Following deployment of the prosthesis 500 in the targeted region, the integrated fastener assembly 502 on the prosthesis 500 is manipulated to anchor the
10 prosthesis 500 to the vessel wall. In the illustrated embodiment, the prosthesis 500 carries two integrated fastener assemblies 502, one in each end region of the prosthesis 500.

In the illustrated embodiment, each fastener
15 assembly 502 is imbedded in a reinforced flange area 506 in the respective end region. Each fastener assembly 502 comprises an array of fasteners 508 circumferentially spaced about the flange 506. The number of fasteners 508 in the array can vary, e.g., from about two to about
20 twelve fasteners on each flange area 506. The configuration of the array can also vary, e.g., in the circumferential array, the fasteners 508 can be axially spaced apart as well.

The fasteners 508 can be formed of a metal or
25 plastic material and can be variously constructed. In the illustrated embodiment, each fastener 508 includes a disc-shaped head 512 and a stem 514 that is bifurcated into two wings 516 and 518, which are joined by a plastic or memory material hinge region 520. The material of the
30 hinge region 520 is formed with a resilient memory that biases the wings 516 and 518 to a spread-apart condition (as Fig. 34 shows).

Each fastener 508 is carried within a grommet 510 on the flange area 506 (see Fig. 35). When the hinge region
35 520 is confined within the grommet 510 (as Fig. 35

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shows), the wings 516 and 518 are retained against the resilient memory in an adjacent, closed condition. In response to the application of a pushing or punching force on the head 512 (see Fig. 35), the wings 516 and 518 are advanced in the closed condition out of the grommet 510, and into and through the adjacent vessel wall (see Fig. 36). Upon continued advancement, the hinge region 520 is freed from the confines of the grommet 510 (see Fig. 37). As a result, the wings 516 and 518 resiliently spring into their normal spread-apart condition.

In this arrangement, an intraluminal tool 522 (see Fig. 33) is deployed into the prosthesis 500 to exert a pushing or punching force upon the head 512 of a given fastener 508. In the illustrated embodiment, the tool 522 comprises a catheter 524 that carries a punch member 526 at its distal end. In a desired arrangement, the distal end of the catheter 524 is steerable, to aid in establishing point contact between the punch member 526 and the head 512 of the given fastener 508. The head 512 can include a recess 528 to receive and stabilize the tip of the punch member 526 with respect to the head 512 during use (see Fig. 34).

In use, the punch member 526 is manipulated to apply a pushing or punching force upon the selected fastener head 512. As Figs. 35 and 36 show, the application of the pushing force by the punch member 526 forces the wings 516 and 518 against the near side of the vessel wall 34. The wings 516 and 518 are still in their closed condition, because the hinge region 520 is still confined within the grommet 510. The closed wings 516 and 518 form an obturator that penetrates tissue as it advances to the far side of the vessel wall. As the hinge region 510 is freed from the grommet 510 (Fig. 37), the wings 516 and 518 resiliently return to their spread-apart

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condition against the far side of the vessel wall. Upon removal of the punch member 526 (see Fig. 38), the head 512 and spread-apart wings 516 and 518 remain in their mutually opposed condition in the vessel wall, to secure
5 the prosthesis 500 against the vessel wall. In use, the physician locates and manipulates the punch member 526 in succession against each fastener 508, to complete the anchorage of the prosthesis 500 to the vessel wall.

In one embodiment (see Fig. 39), each fastener 508
10 can include a tracking wire 530 that is releasably coupled to the head 512. The tracking wire 530 extends from the head 512 outside the body for access outside the vessel. In this arrangement, the punch member 526 includes a lumen to accommodate passage of the tracking
15 wire 530. The tracking wire 530 guides the punch member 526 in an intraluminal path to the respective fastener 508. After the punch member 526 is manipulated to drive the fastener 508 into the vessel wall, the punch member 526 can be withdrawn over the tracking wire 530. The
20 tracking wire 530 can be released from the now-secured head 512, e.g., by applying a moderate pulling force upon the tracking wire 530. The tracking wire 530 can then be withdrawn. The punch member 526 is sequentially guided over another tracking wire 530 for interaction with
25 another one of the fasteners 508, until a desired degree of anchorage is achieved.

In an alternative embodiment, an integrated fastener assembly 502 on the prosthesis 500 can be used to temporarily tack the prosthesis 500 in place while a
30 permanent anchoring technique is carried out. For example, in this arrangement, after using the integrated fastener assembly 502 to temporarily hold the prosthesis 500 in a desired location, the separate helical fasteners 28 are deployed in the manner previously described, to
35 permanently anchor the prosthesis 500 against the vessel

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wall.

It will be appreciated that the components and/or features of the preferred embodiments described herein may be used together or separately, while the depicted
5 methods and devices may be combined or modified in whole or in part. It is contemplated that the components of the directing device, fastener applier and helical fastener may be alternately oriented relative to each other, for example, offset, bi-axial, etc. Further, it will be
10 understood that the various embodiments may be used in additional procedures not described herein, such as vascular trauma, arterial dissections, artificial heart valve attachment and attachment of other prosthetic device within the vascular system and generally within
15 the body.

The preferred embodiments of the invention are described above in detail for the purpose of setting forth a complete disclosure and for the sake of explanation and clarity. Those skilled in the art will
20 envision other modifications within the scope and spirit of the present disclosure.

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WHAT IS CLAIMED IS:

1. A fastener applier for a prosthesis comprising:
 - a drive mechanism sized and configured to be
5 releasably coupled to the fastener to deploy the fastener into the prosthesis, and
 - an actuator for the drive mechanism including a sensing mechanism that enables operation of the drive mechanism in response to a force sensed at or near the
10 fastener.
2. A fastener applier according to claim 1 wherein the sensing mechanism disables operation of the drive mechanism when force sensed is less than a predetermined magnitude.
- 15 3. A fastener applier according to claim 1 wherein the sensing mechanism includes a switch assembly that is actuated in response to force sensed at or near the fastener.
4. A fastener applier for a prosthesis
20 comprising:
 - a drive mechanism sized and configured to be releasably coupled to the fastener to deploy the fastener into the prosthesis, and
 - an actuator for the drive mechanism including
25 a sensing mechanism that enables operation of the drive mechanism in response to contact sensed with a surface at or near the fastener.
5. A fastener applier according to claim 4 wherein the sensing mechanism disables
30 operation of the drive mechanism in the absence of contact sensed.
6. A fastener applier according to claim 4 wherein the sensing mechanism includes a switch assembly that is actuated in response to contact

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sensed at or near the fastener.

7. A fastener applier according to claim 1
or 4

5 wherein the drive mechanism includes a carrier
for the fastener.

8. A fastener applier according to claim 7
wherein the carrier receives a single fastener
at a time.

10 9. A fastener applier according to claim 1
or 4

wherein the drive mechanism is magnetically
coupled to the fastener.

15 10. A fastener applier according to claim 9
wherein the drive mechanism is magnetically
coupled to a single fastener at a time.

11. A fastener applier according to claim 1
or 4

wherein the drive mechanism is mechanically
coupled to the fastener.

20 12. A fastener applier according to claim 11
wherein the drive mechanism is mechanically
coupled to a single fastener at a time.

13. A fastener applier according to claim 1
or 4

25 wherein the drive mechanism rotates the
fastener for deployment.

14. A fastener applier according to claim 1
or 4

30 further including a catheter body sized and
configured for deployment in a targeted body region, and
wherein at least a portion of the drive
mechanism is carried by the catheter body.

35 15. A fastener applier according to claim 14
wherein the catheter body includes a distal
end, and

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wherein the sensing mechanism includes a component extending distally beyond the distal end of the catheter body.

5 16. A fastener applier according to claim 15 wherein the component includes a carrier for the fastener.

 17. A fastener applier according to claim 15 wherein the component includes a force sensing probe.

10 18. A fastener applier according to claim 1 or 4

 further including a catheter body sized and configured for intraluminal passage, and

 wherein at least a portion of the drive mechanism is carried by the catheter body for deployment in a targeted endovascular region.

 19. A fastener applier according to claim 18 wherein the catheter body includes a distal end, and

20 wherein the sensing mechanism includes a component extending distally beyond the distal end of the catheter body.

 20. A fastener applier according to claim 19 wherein the component includes a carrier for the fastener.

 21. A fastener applier according to claim 19 wherein the component includes a sensing probe.

30 22. A fastener sized and configured for singular deployment in tissue comprising

 a fastener body having a distal end for penetrating tissue in response to a force and a proximal end for releasably coupling the fastener body to a force applier, and

35 a stop structure associated with the proximal

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end to prevent over-penetration of the fastener body into tissue.

23. A fastener according to claim 22
wherein the fastener body comprises a helical
5 coil having an interior diameter, and
wherein the stop structure comprises a leg of
the coil that extends substantially across the entire
interior diameter.

24. A fastener according to claim 23
10 wherein the leg mechanically couples the
fastener body to the force applier.

25. A fastener according to claim 22
wherein the fastener body comprises a helical
coil having an interior diameter, and
15 wherein the stop structure comprises a cap
that extends substantially across the entire interior
diameter.

26. A fastener according to claim 25
wherein the cap includes a fitting to engage
20 the force applier.

27. A fastener according to claim 25
wherein the cap includes a material that is
magnetized.

28. A fastener according to claim 25
25 wherein the cap includes a material that is
attracted to a magnetized material.

29. A fastener according to claim 22
wherein the stop structure couples the
fastener body to the force applier.

30. A fastener according to claim 29
30 wherein the stop structure includes a material
that is magnetized.

31. A fastener according to claim 29
wherein the stop structure includes a material
35 that is attracted to a magnetized material.

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32. A fastener according to claim 29
wherein the stop structure mechanically
couples the fastener body to the force applier.

5 33. A fastener according to claim 22
wherein the fastener body comprises a helical
coil.

34. A system for applying a fastener to a
prosthesis within a body comprising
a fastener comprising a body having a distal
10 end for penetrating tissue in response to a force and
proximal end,

a drive mechanism sized and configured to be
releasably coupled to the proximal end of the fastener
body to apply force, and

15 an actuator for the drive mechanism including
a sensing mechanism that enables operation of the drive
mechanism in response to at least one of force sensed at
or near the distal end of the fastener body, or (ii)
contact sensed with a surface at or near the distal end
20 of the fastener body.

35. A system according to claim 34
wherein the fastener includes a stop structure
associated with the proximal end to prevent over-
penetration of the fastener body into tissue.

25 36. A system according to claim 34
wherein the drive mechanism is sized and
configured to be releasably coupled to a single fastener
at a time.

37. A system according to claim 34
30 further including a catheter body sized and
configured for deployment in a targeted body region, and
wherein at least a portion of the drive
mechanism is carried by the catheter body.

38. A system according to claim 34
35 further including a catheter body sized and

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configured for intraluminal passage, and

wherein at least a portion of the drive mechanism is carried by the catheter body for deployment in a targeted endovascular region.

5 39. A system for applying a fastener to a prosthesis within a body comprising

a fastener comprising a body having a distal end for penetrating tissue in response to a force and proximal end that includes a stop structure to prevent
10 over-penetration of the fastener body into tissue, and

a drive mechanism sized and configured to be releasably coupled to the stop structure to apply force.

40. A system according to claim 39 wherein the drive mechanism is sized and
15 configured to be releasably coupled to a single fastener at a time.

41. A system according to claim 39 further including a catheter body sized and configured for deployment in a targeted body region, and
20 wherein at least a portion of the drive mechanism is carried by the catheter body.

42. A system according to claim 39 further including a catheter body sized and configured for intraluminal passage, and
25 wherein at least a portion of the drive mechanism is carried by the catheter body for deployment in a targeted endovascular region.

43. A prosthesis comprising a prosthesis body,
30 a fastener assembly integrally carried by the prosthesis body, the assembly including at least one fastener deployable into tissue in response to force applied by a force applier, and

a tracking wire coupled to the fastener to
35 guide the force applier into operative contact with the

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fastener.

44. A prosthesis comprising
a prosthesis body, and
a fastener assembly integrally carried by the
5 prosthesis body, the assembly including at least one
fastener deployable into tissue in response to non-
rotational force applied by a force applier.

45. A prosthesis according to claim 44
further including a tracking wire coupled to
10 the fastener to guide the force applier into operative
contact with the fastener.

46. A fastener sized and configured for
singular deployment in tissue comprising
a fastener body having a distal end for
15 penetrating tissue in response to a force and proximal
end for releasably coupling the fastener body to a force
applier, and

a tracking wire coupled to the proximal end to
guide the force applier into operative contact with the
20 fastener.

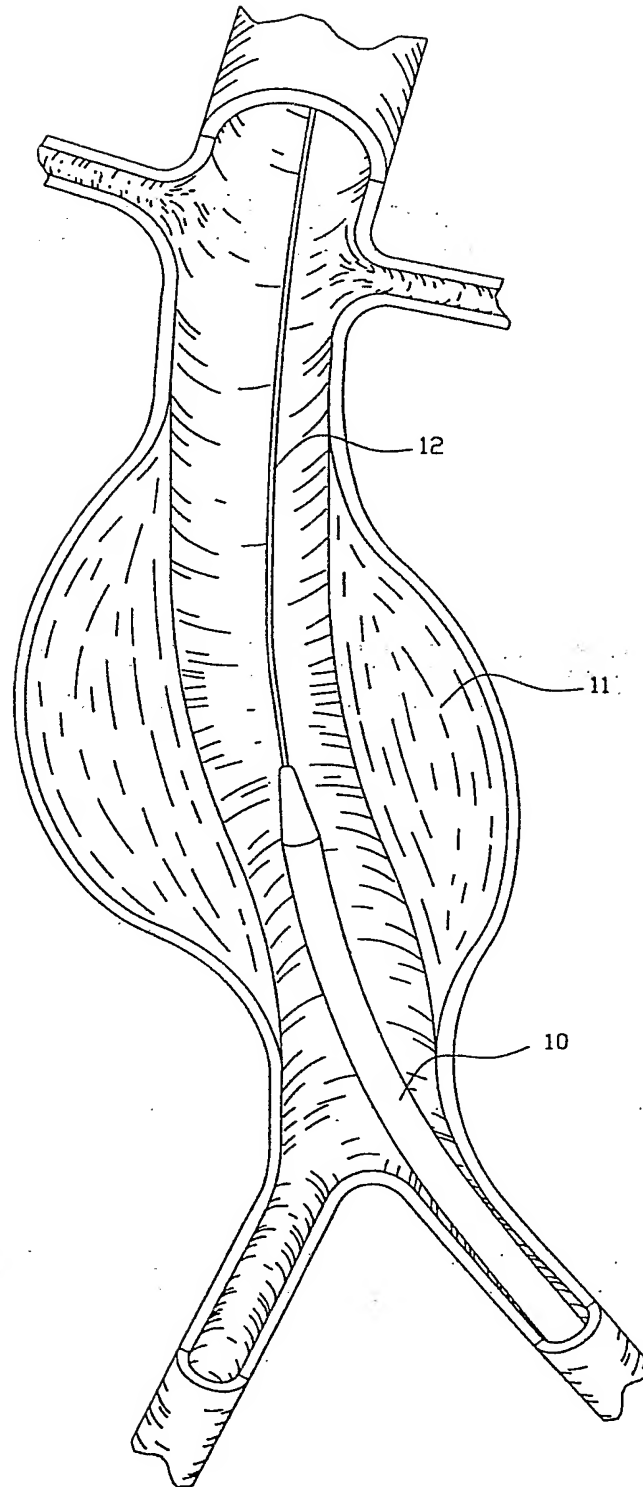


Fig. 1

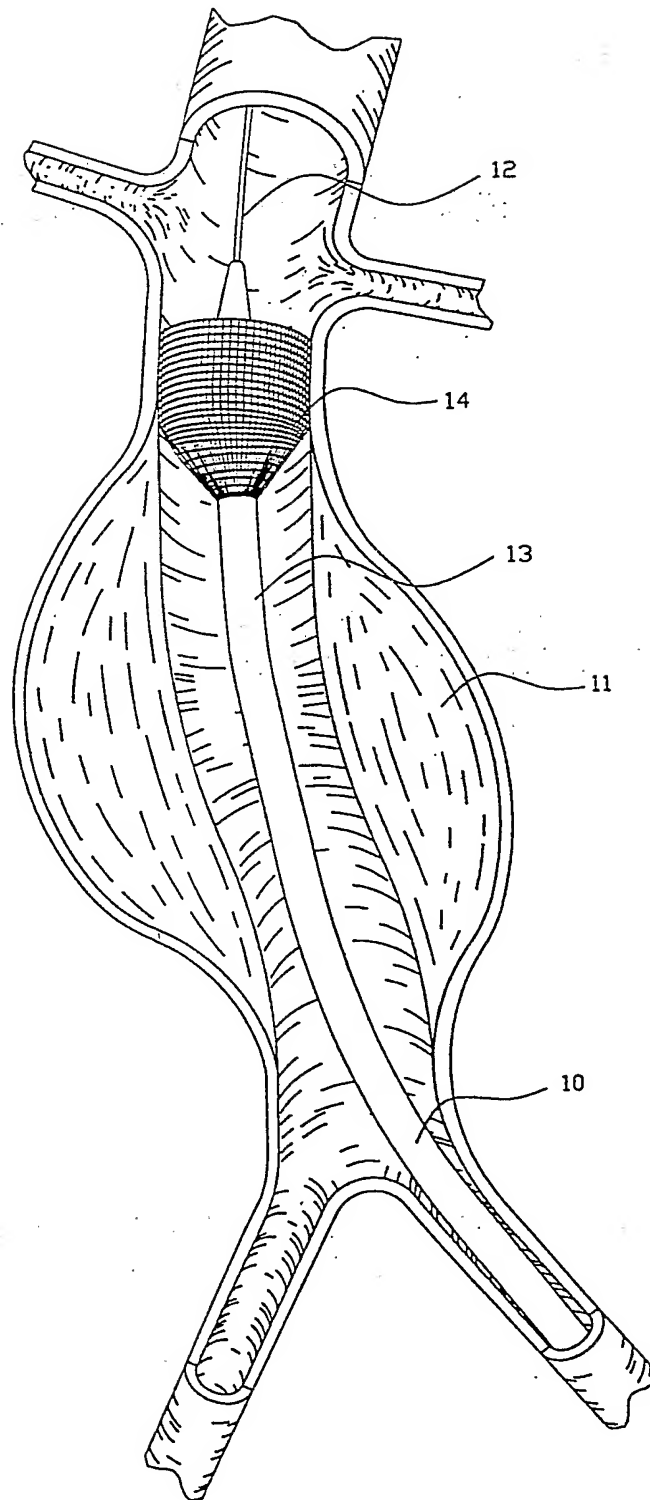


Fig. 2

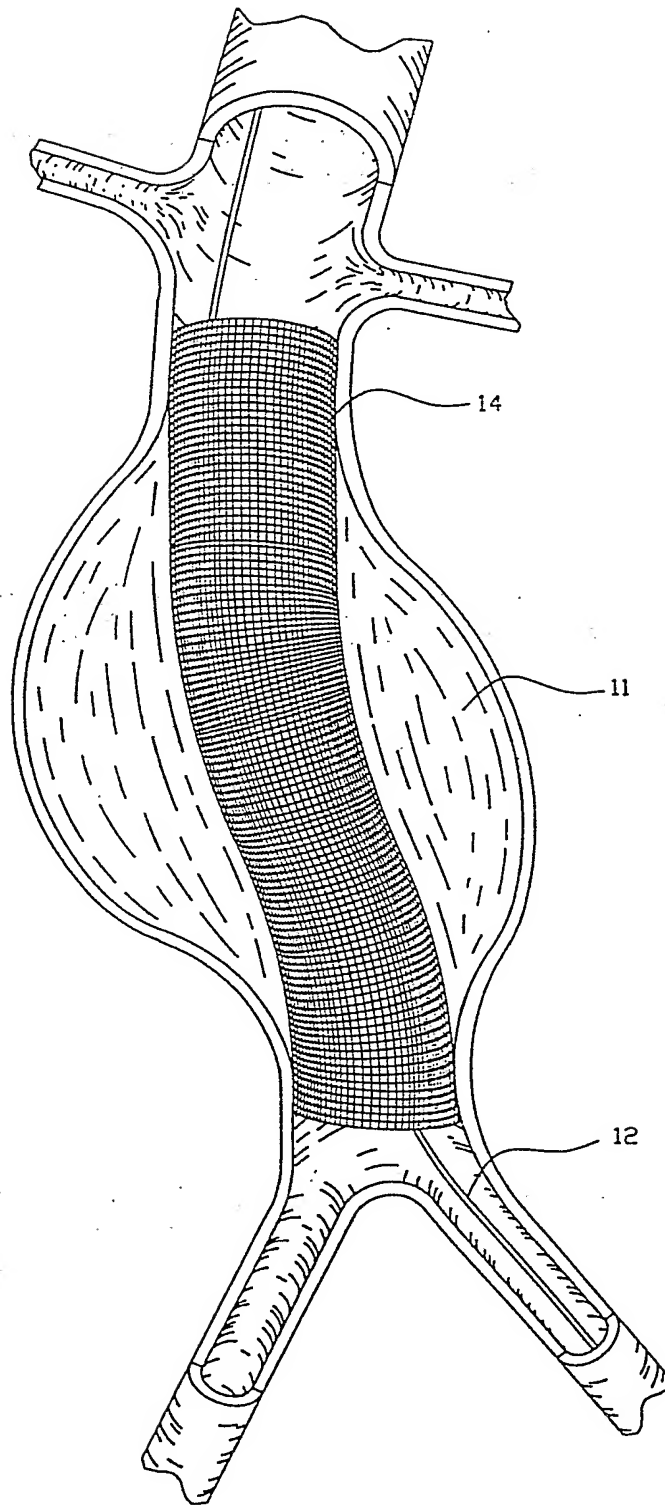


Fig. 3

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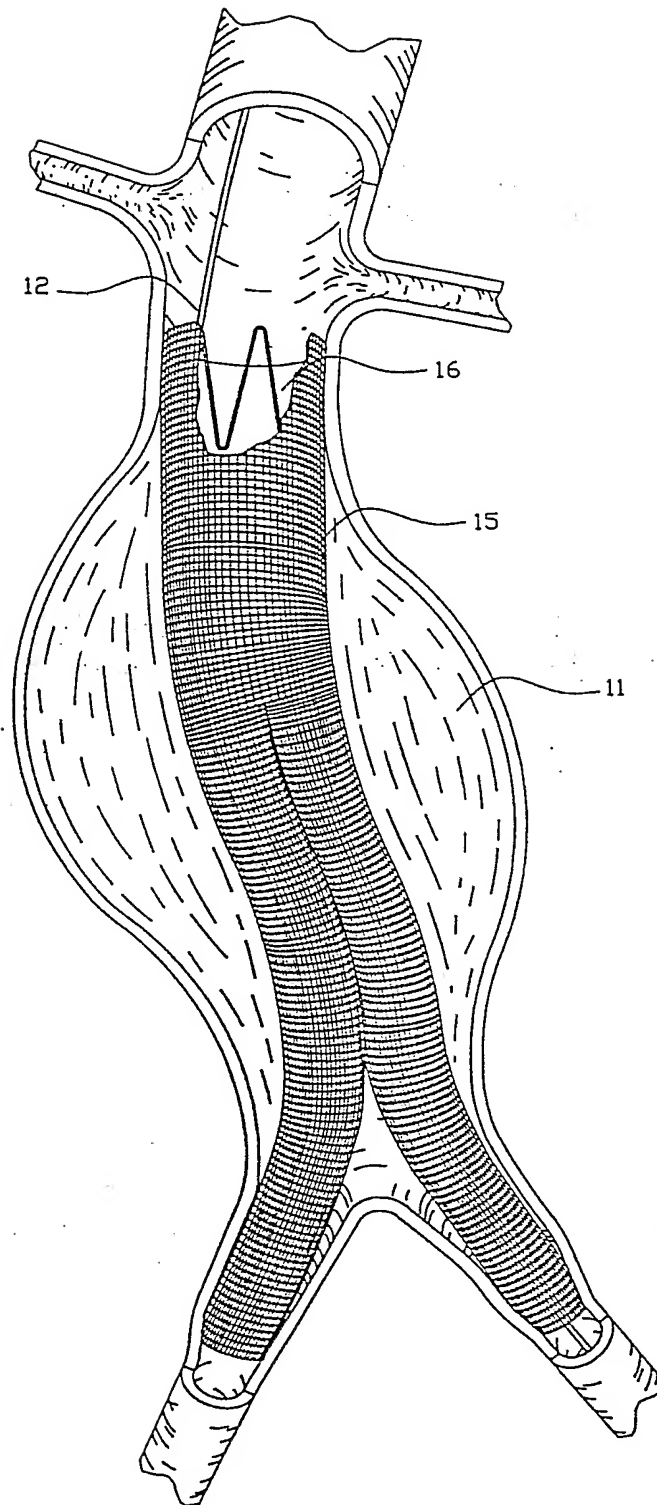


Fig. 4

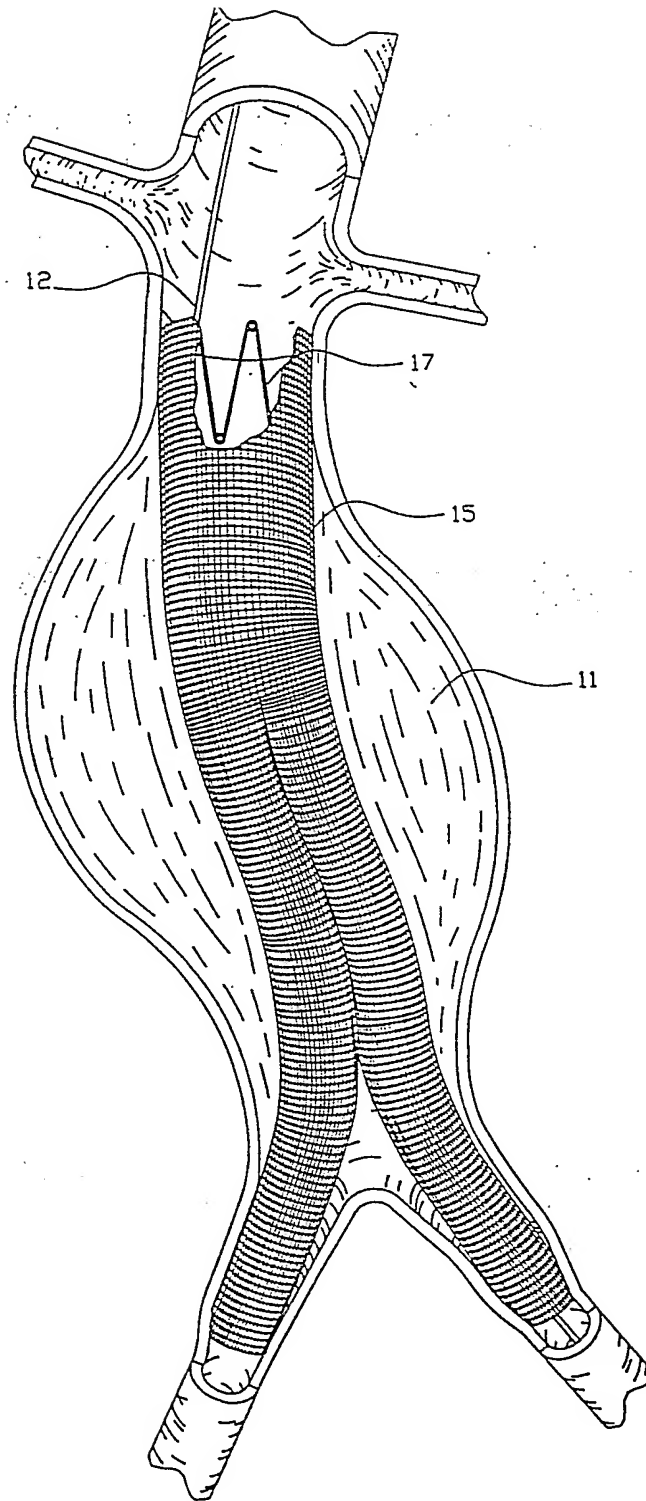


Fig. 5

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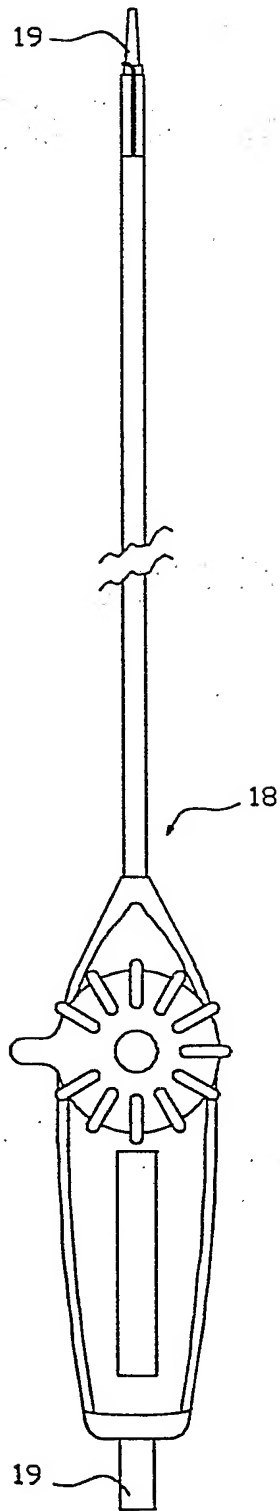


Fig. 6

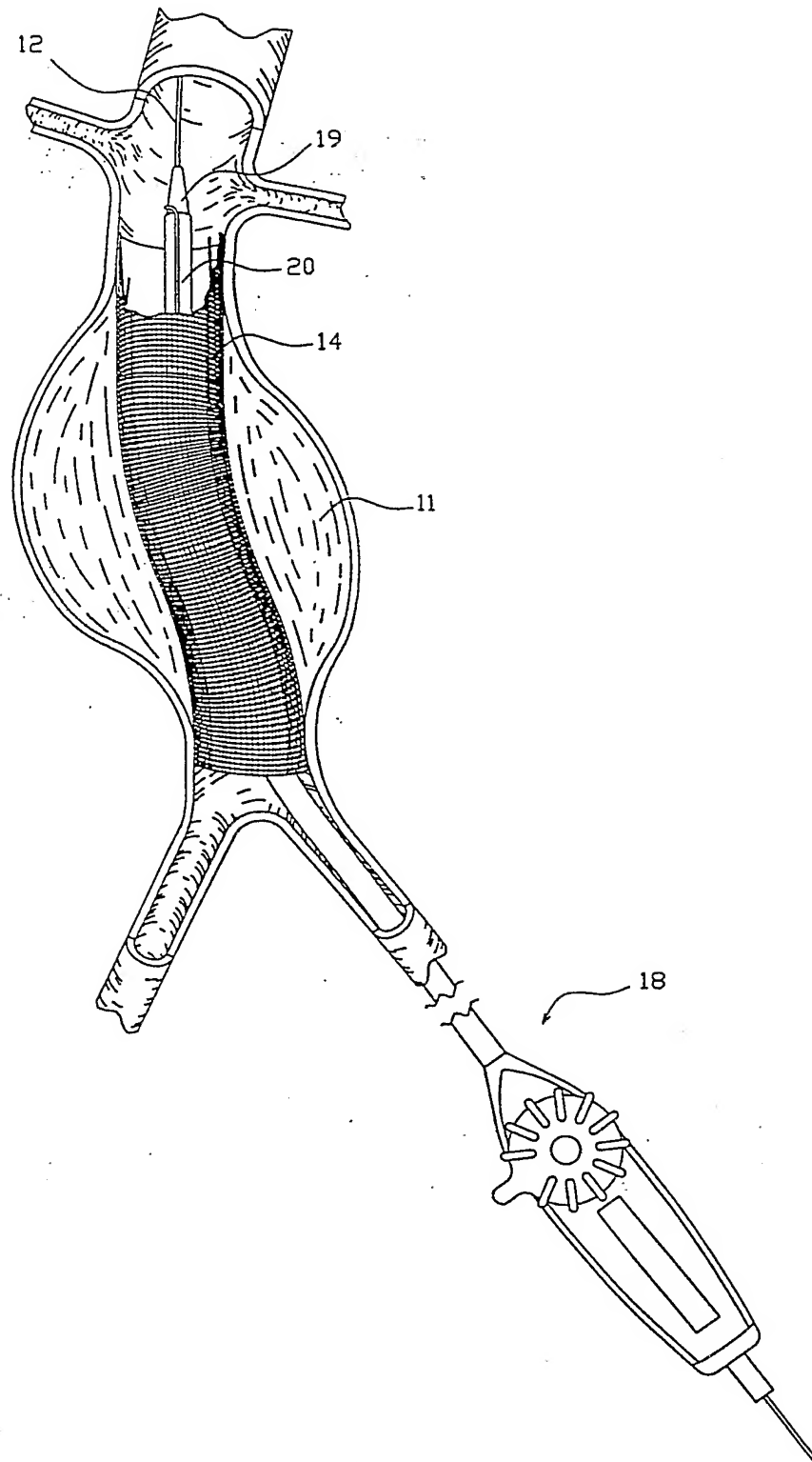


Fig. 7

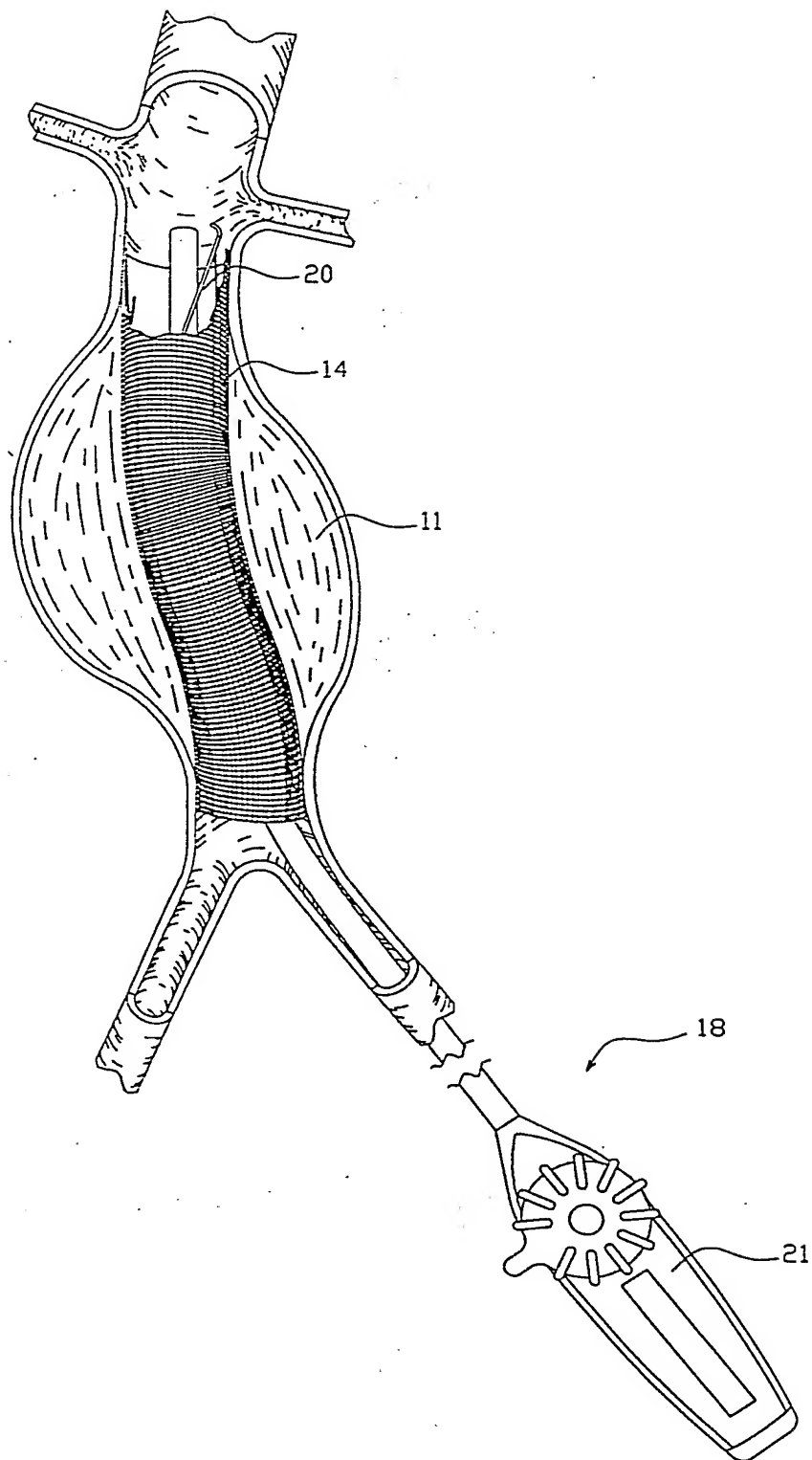


Fig. 8

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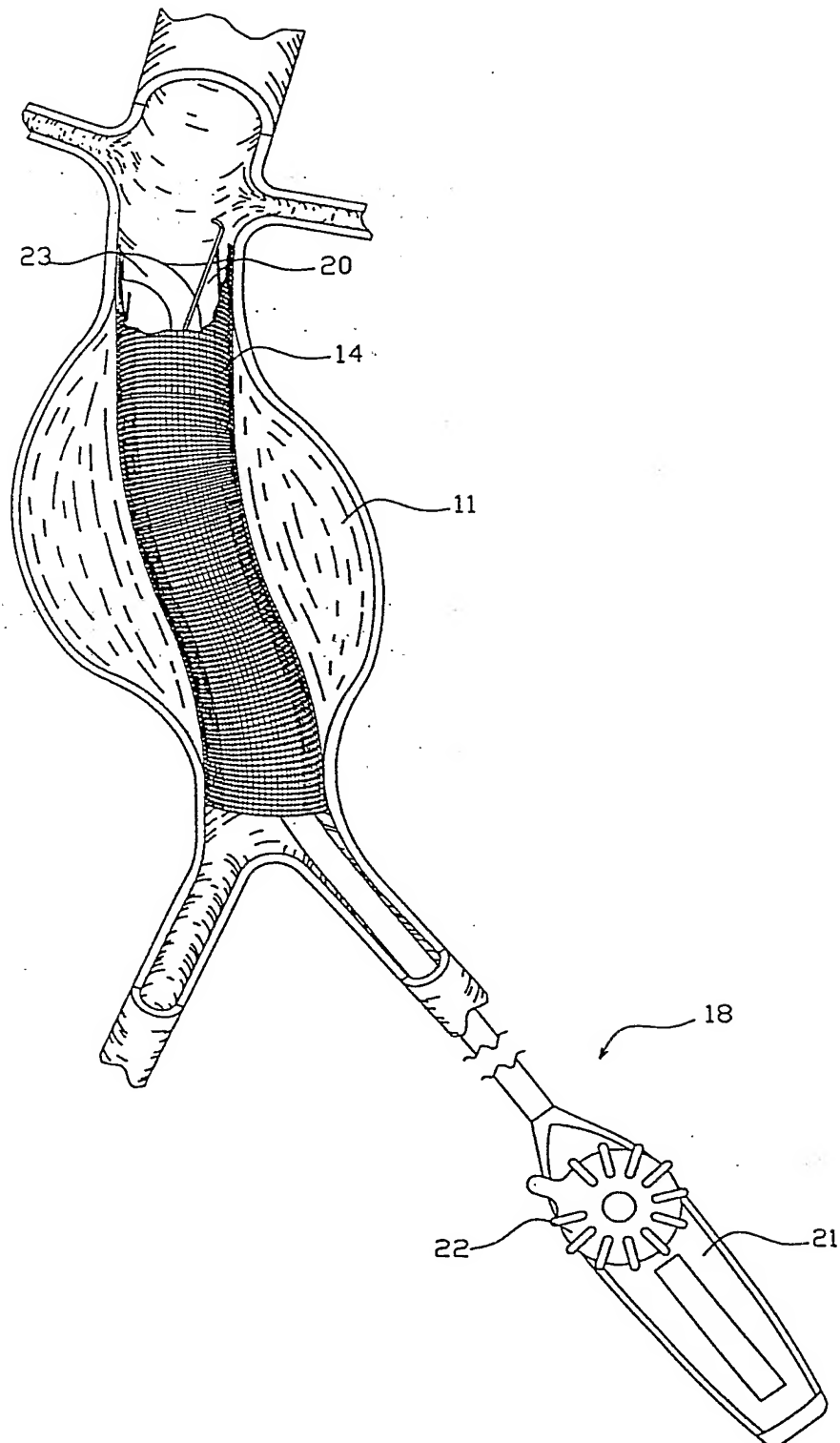


Fig. 9

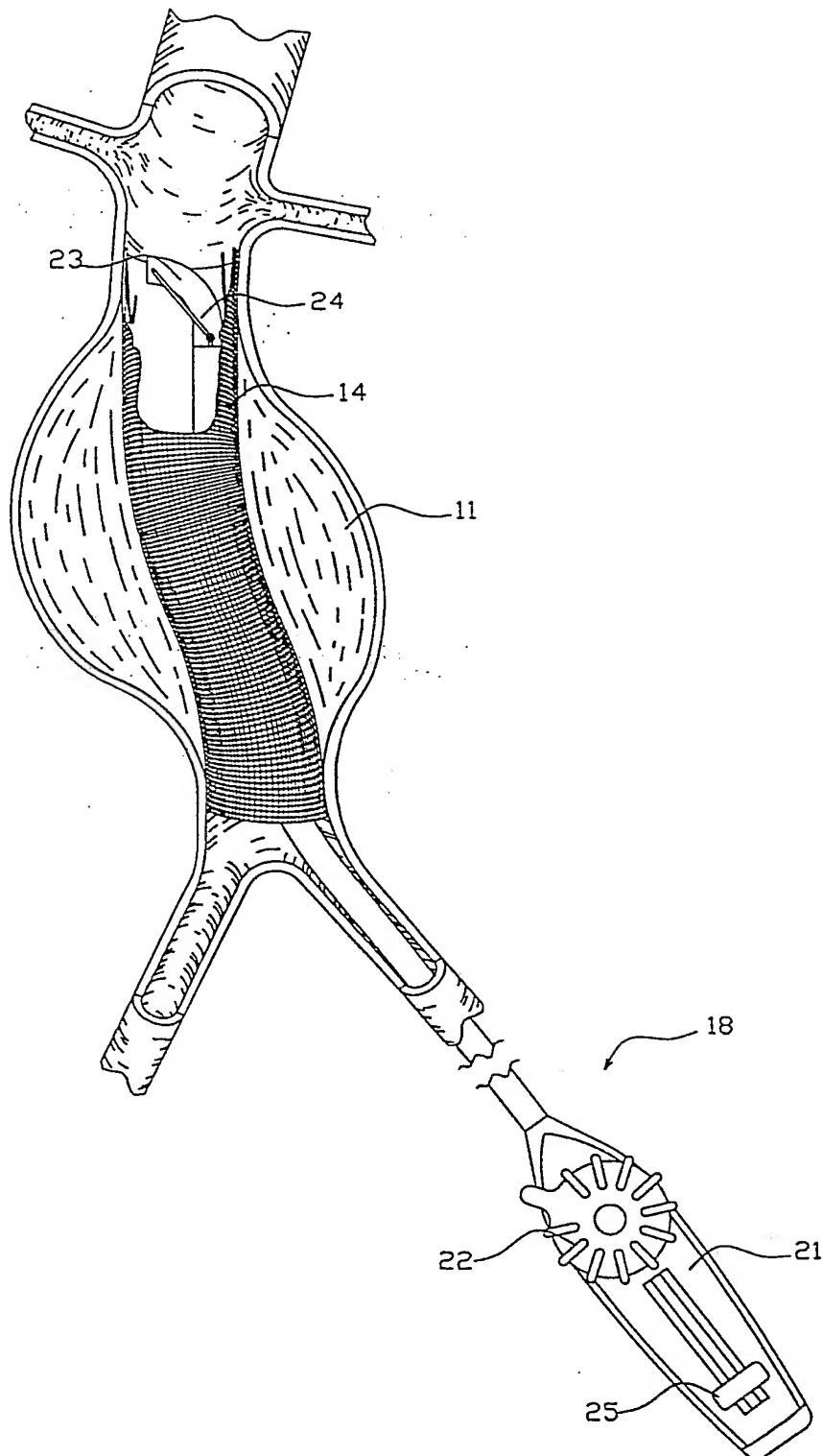


Fig. 10

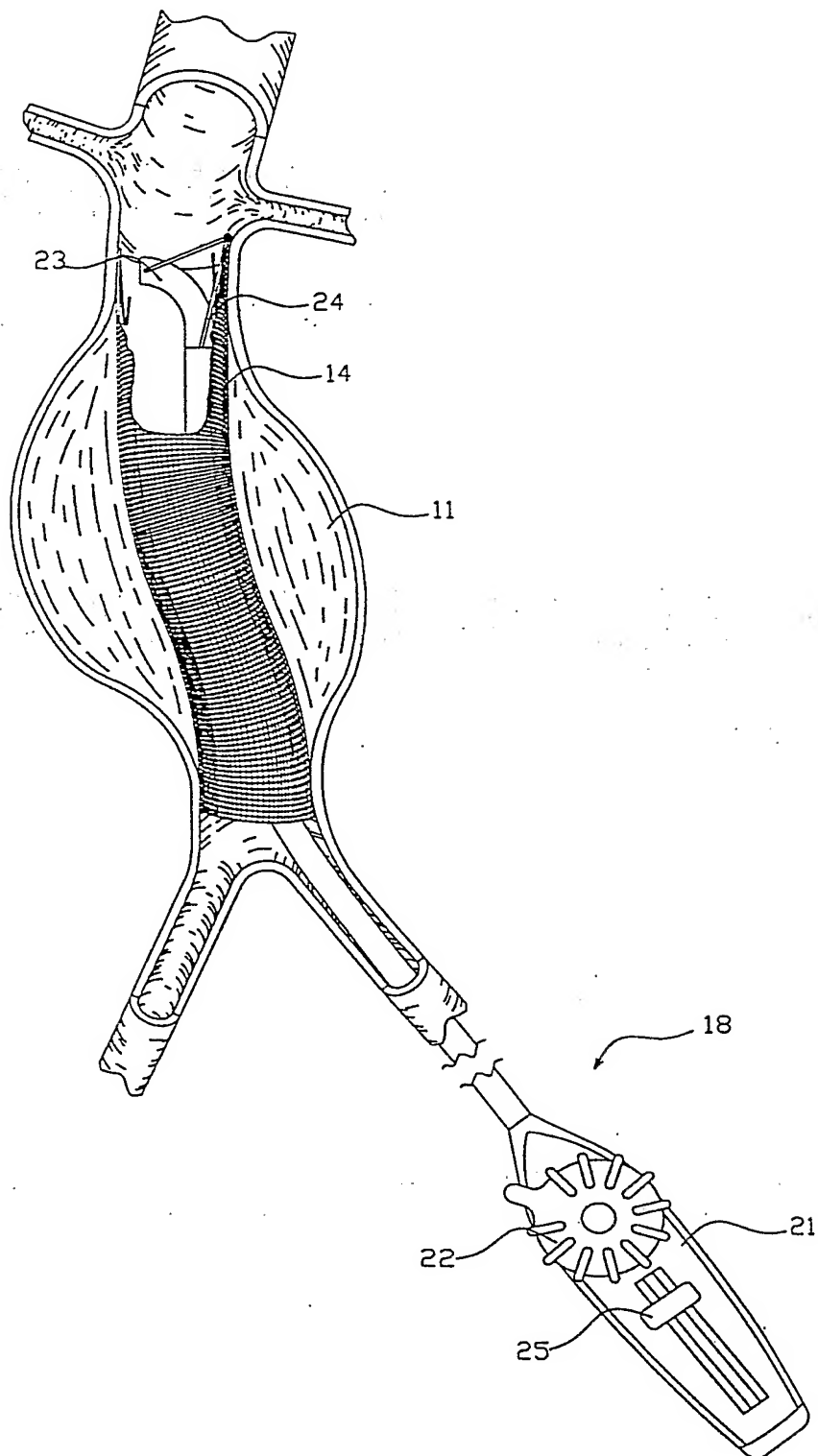


Fig. 11

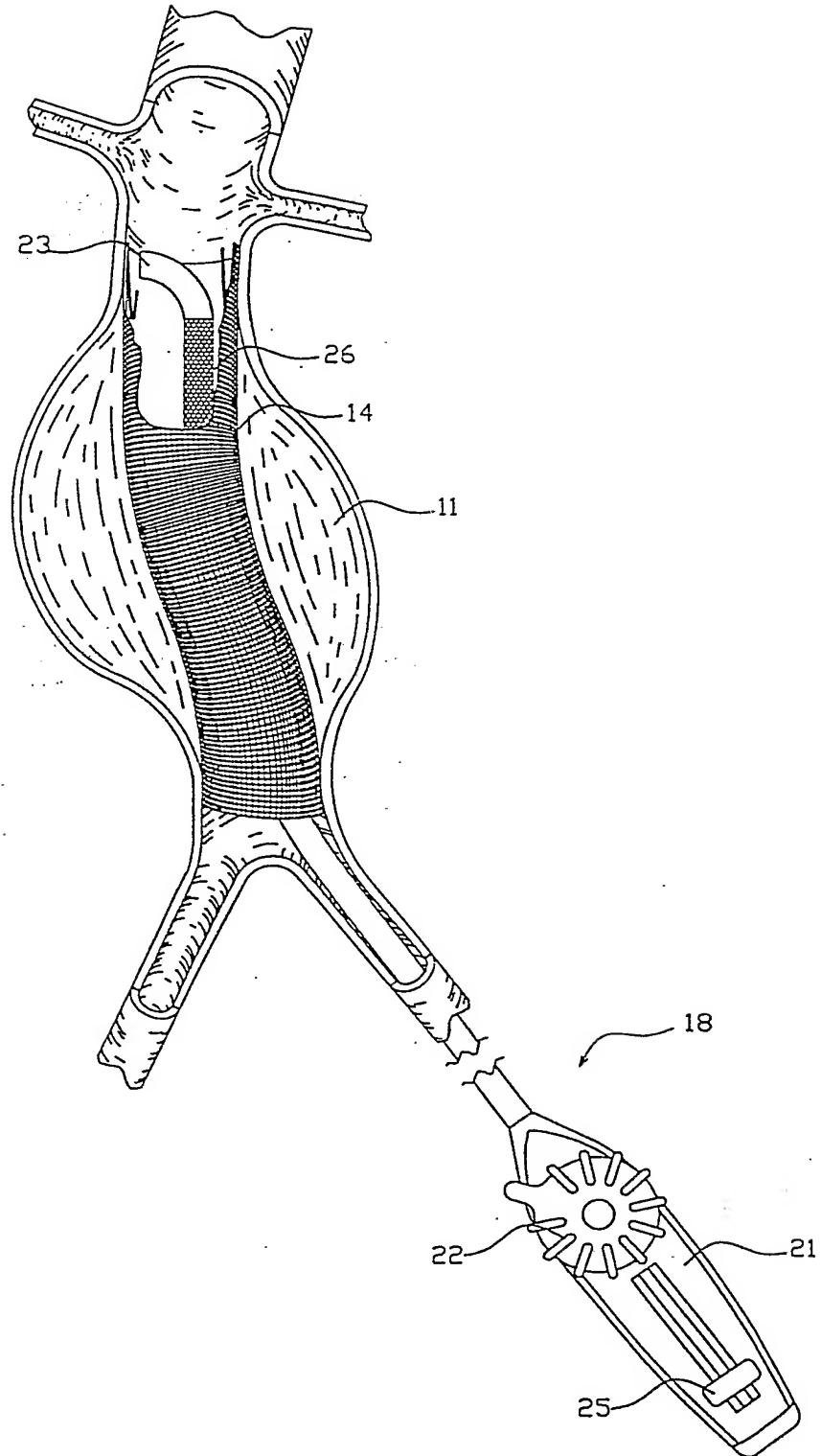


Fig. 12

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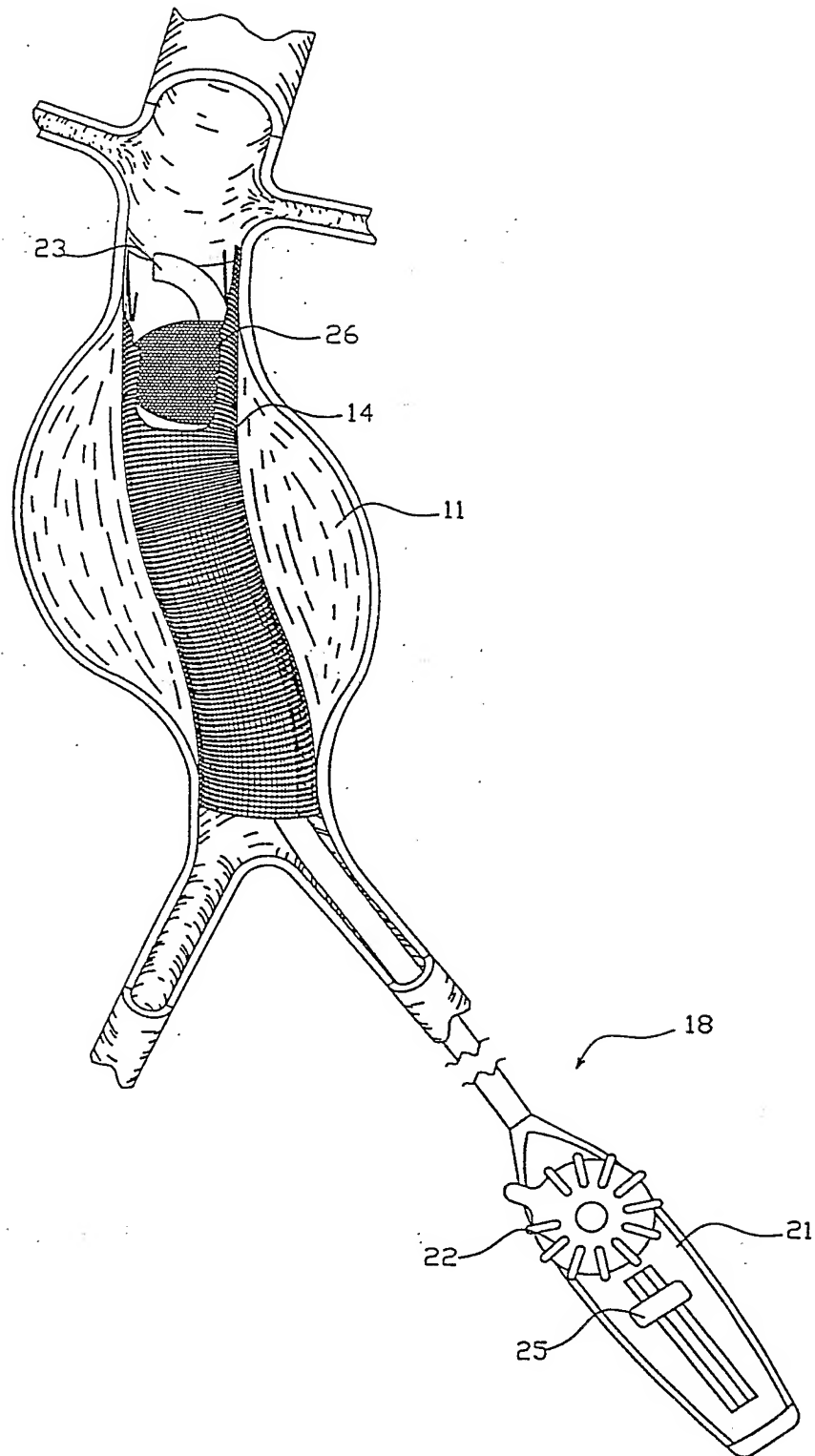


Fig. 13

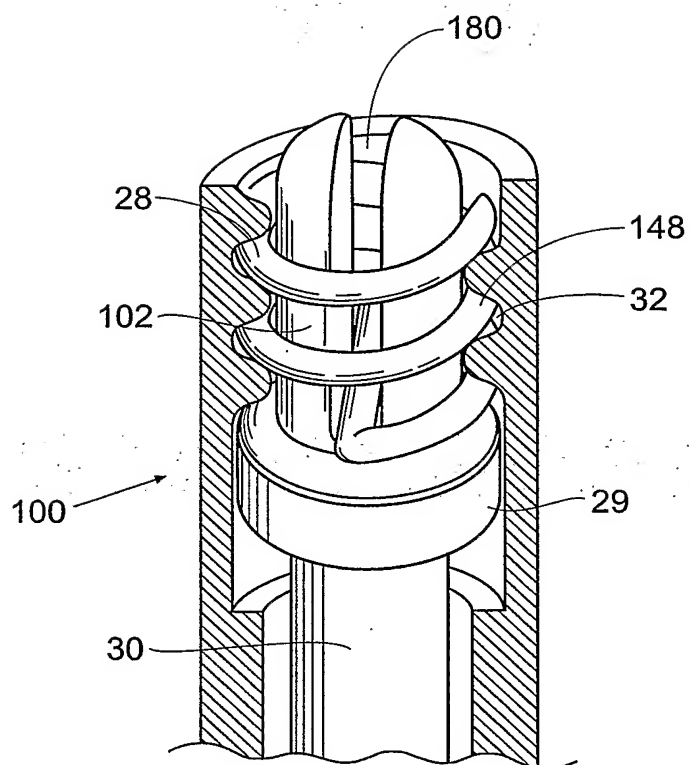


Fig. 14A

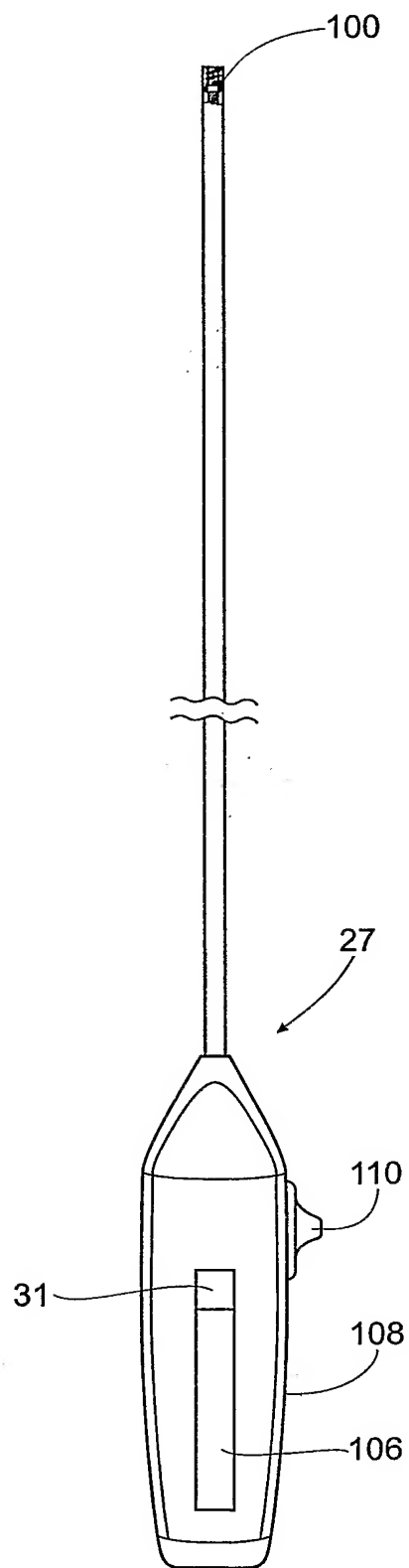
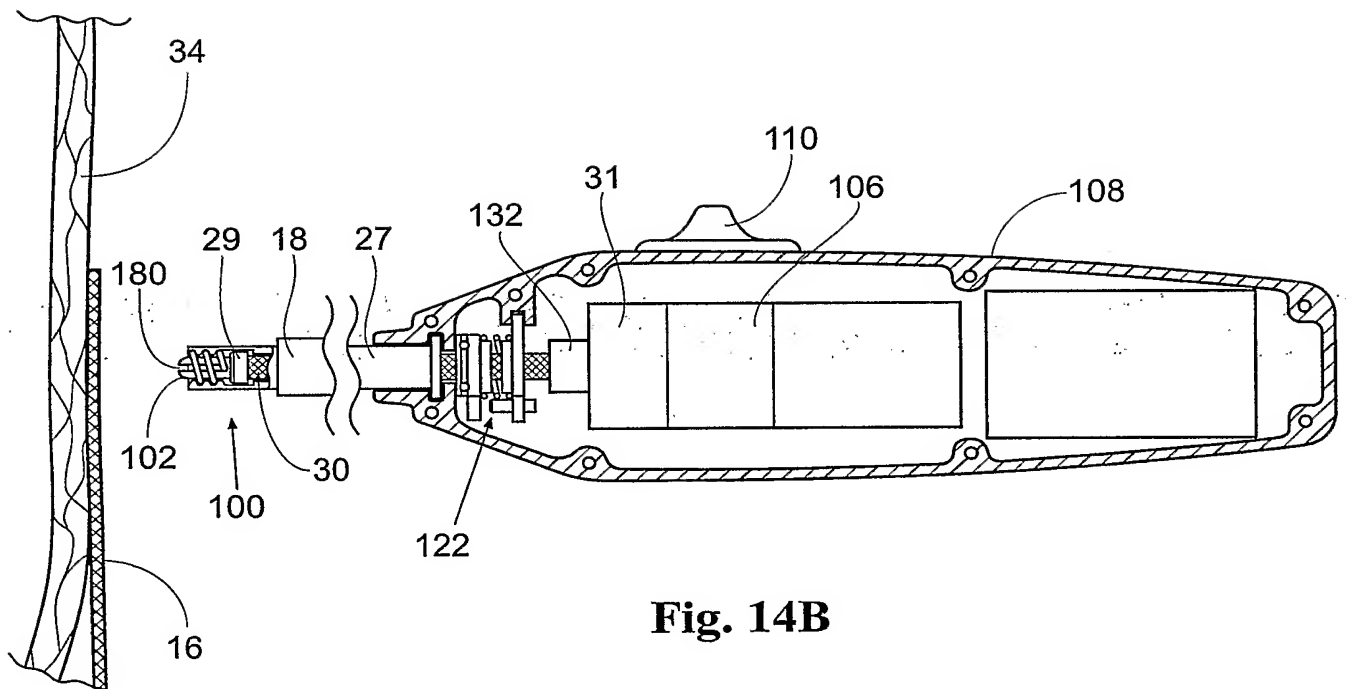


Fig. 14

**Fig. 14B**

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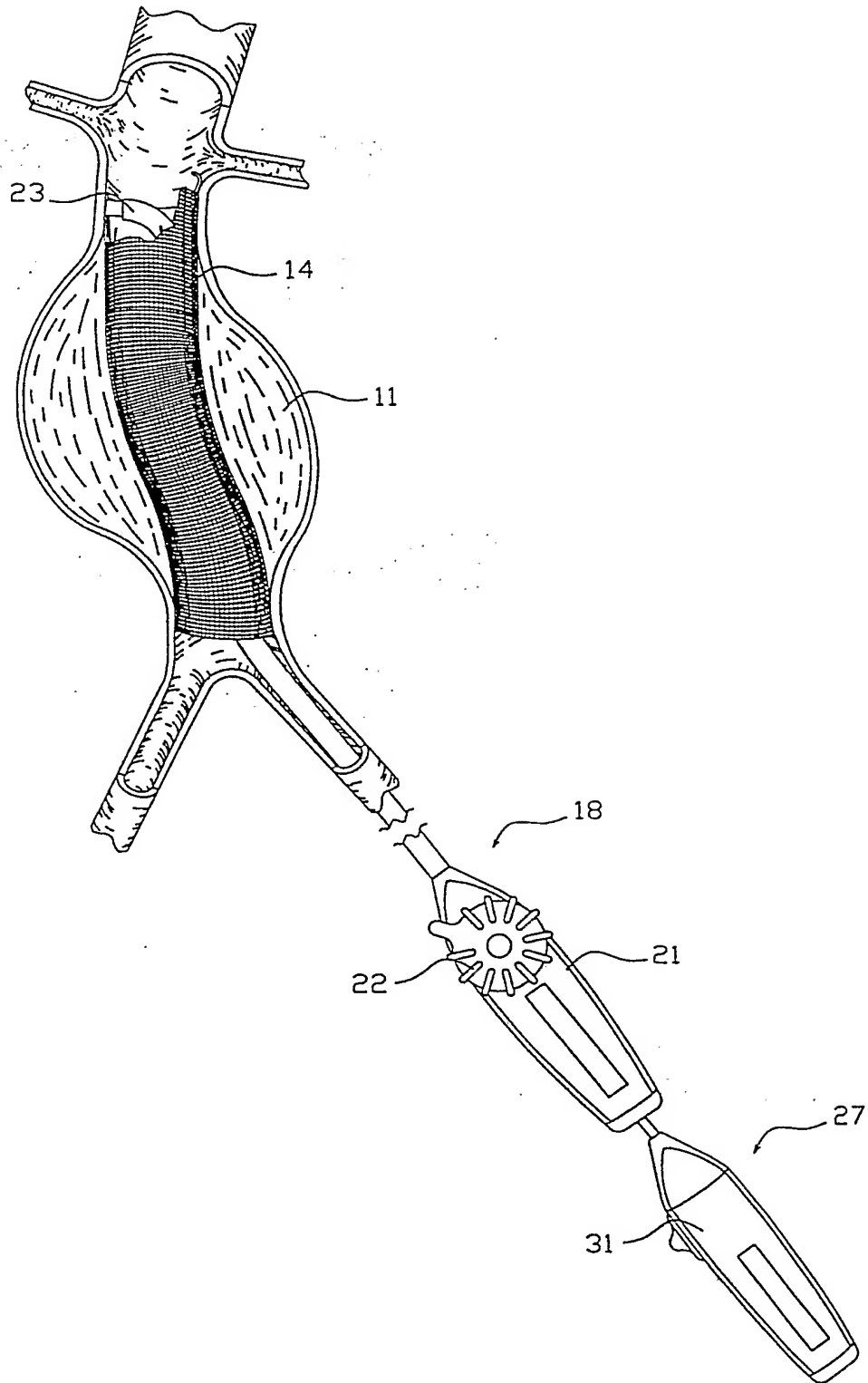


Fig. 15

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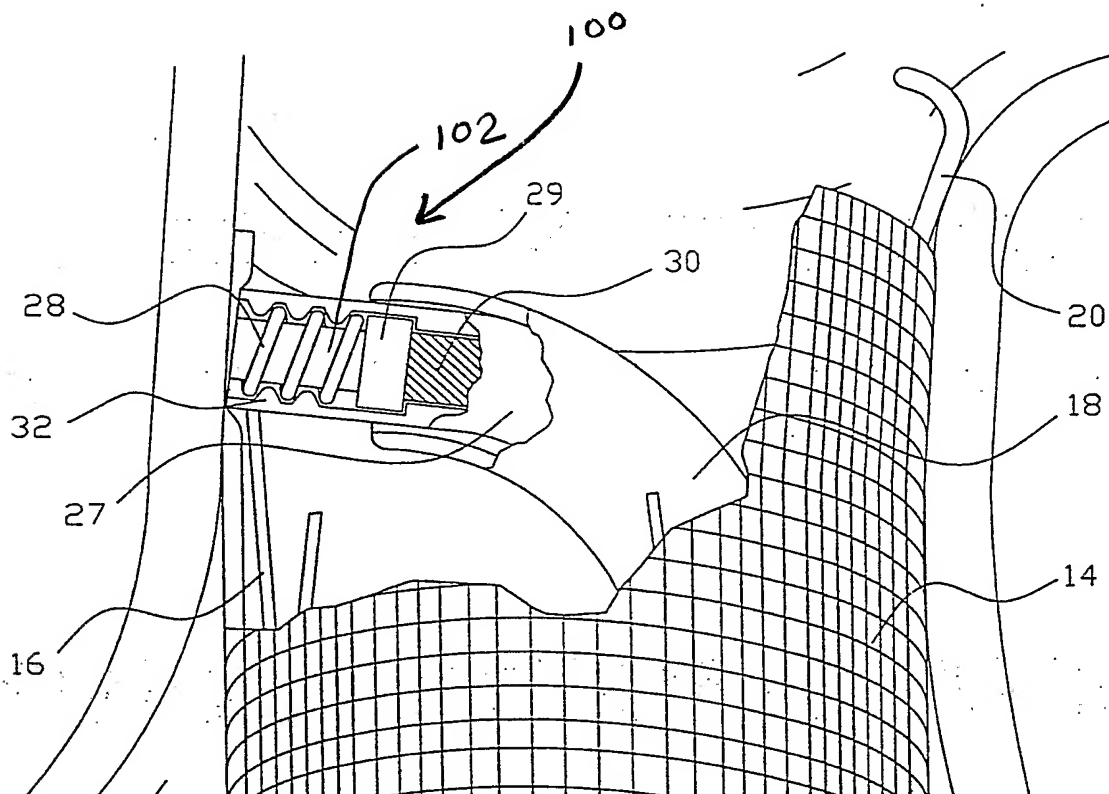


Fig. 16

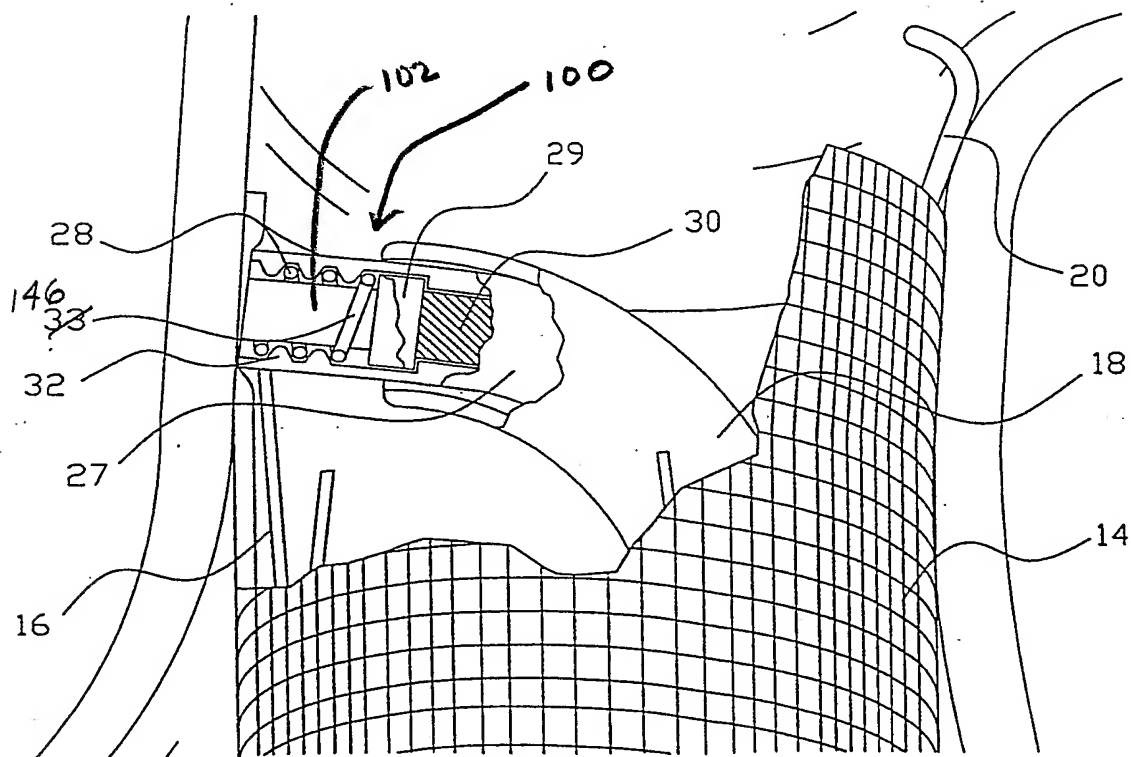


Fig. 17

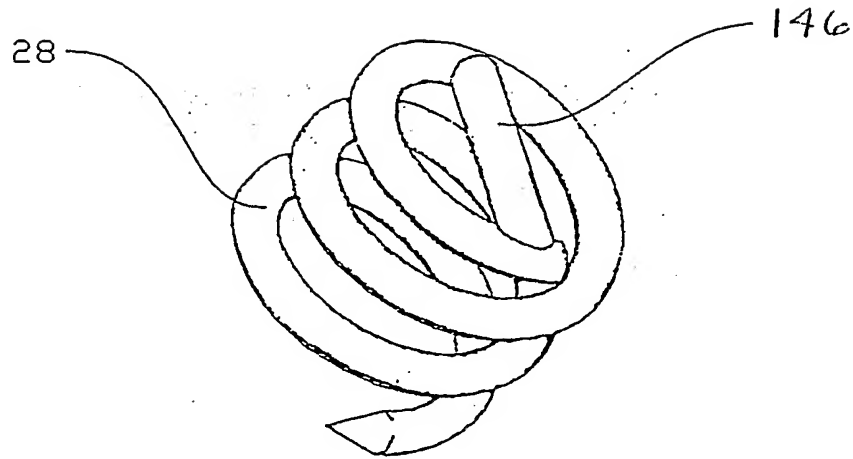


Fig. 18

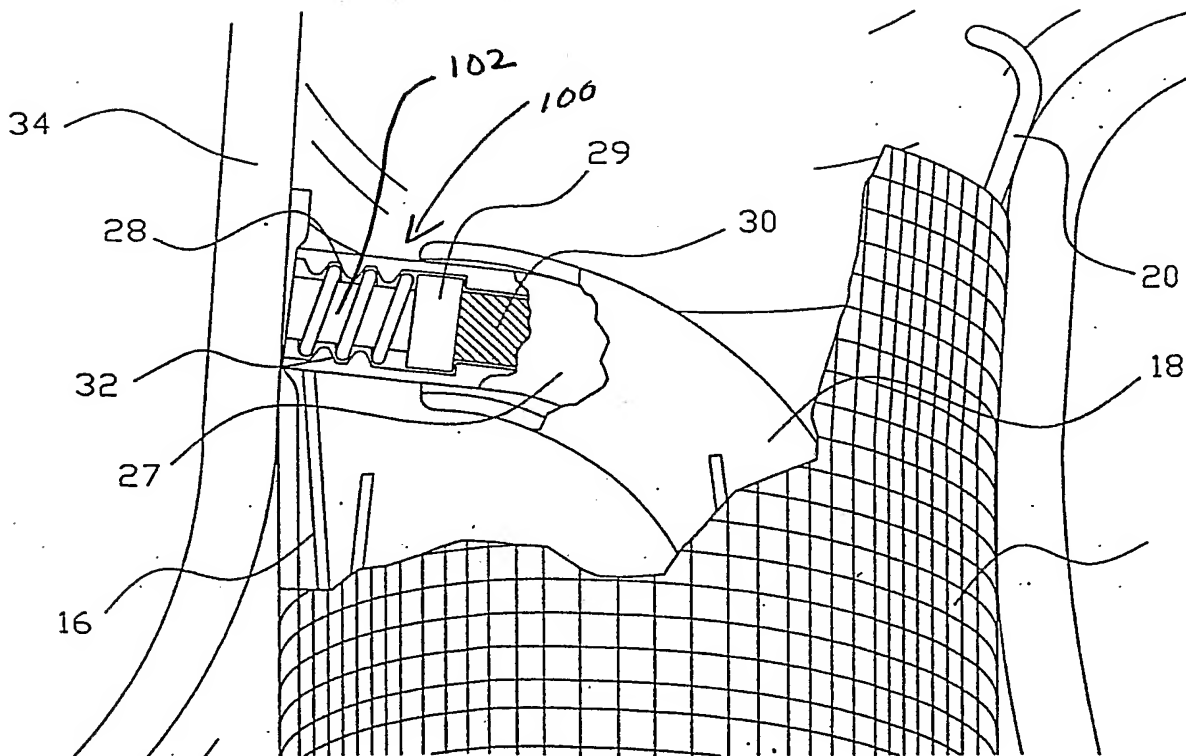


Fig. 19

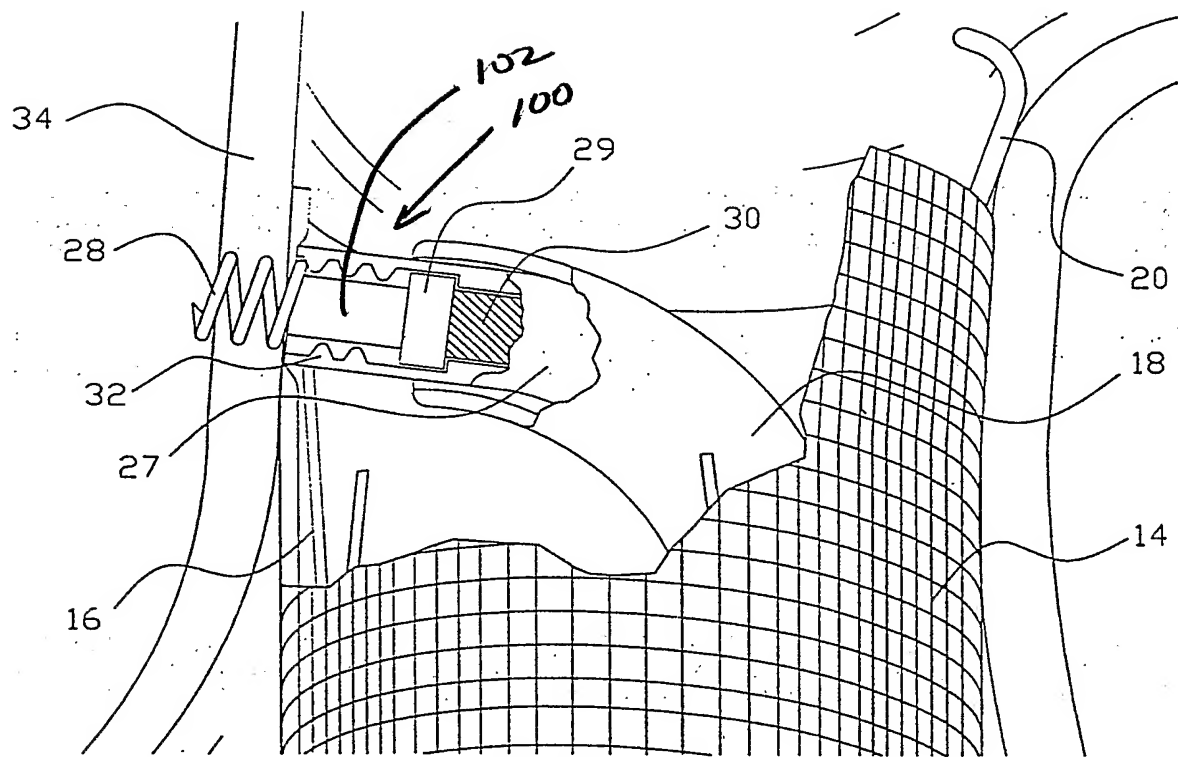


Fig. 20

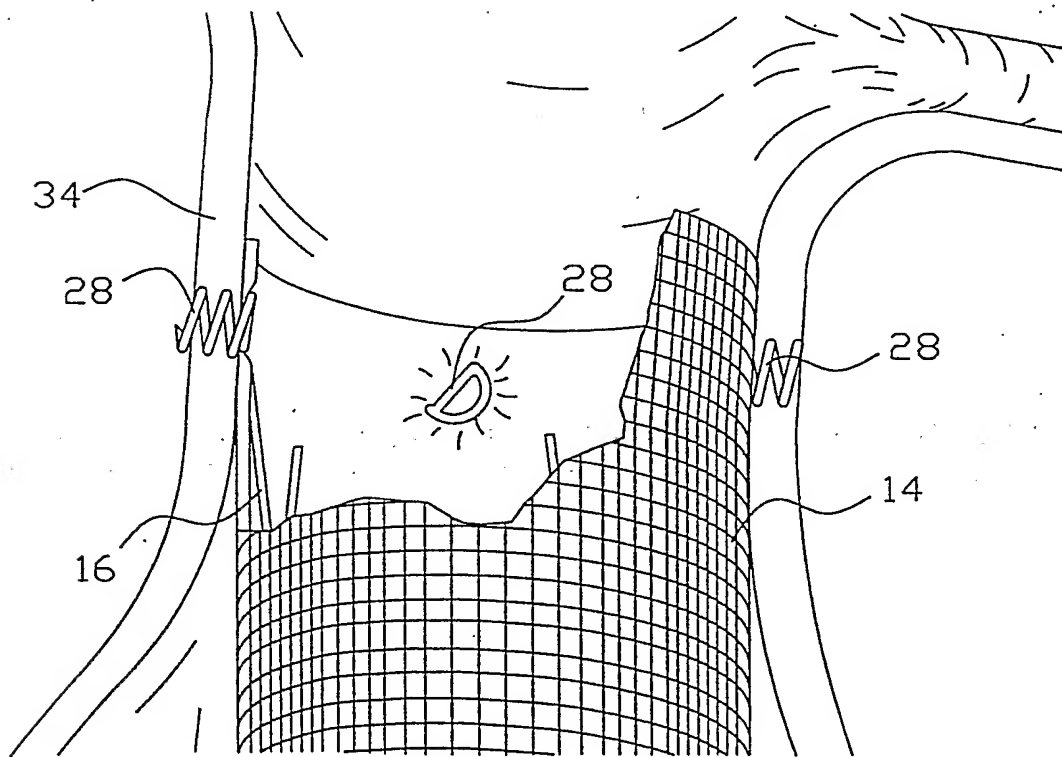


Fig. 21

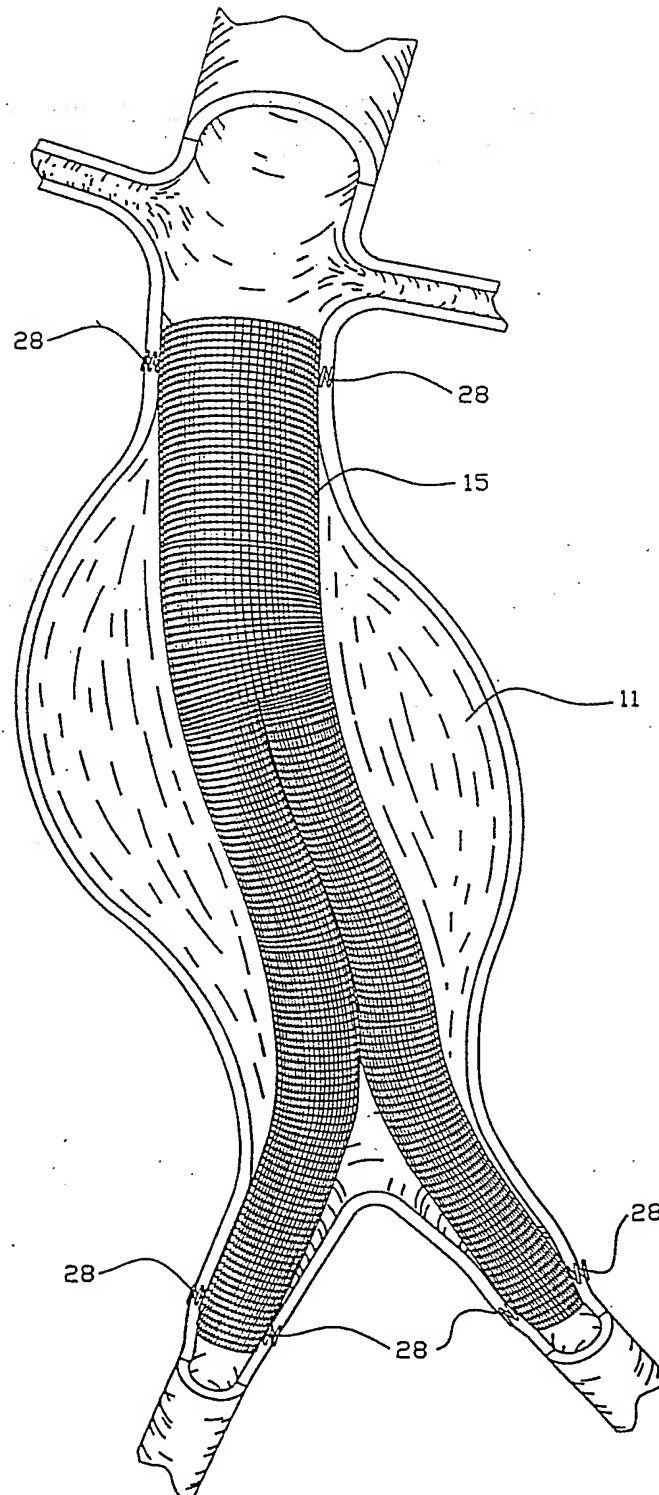
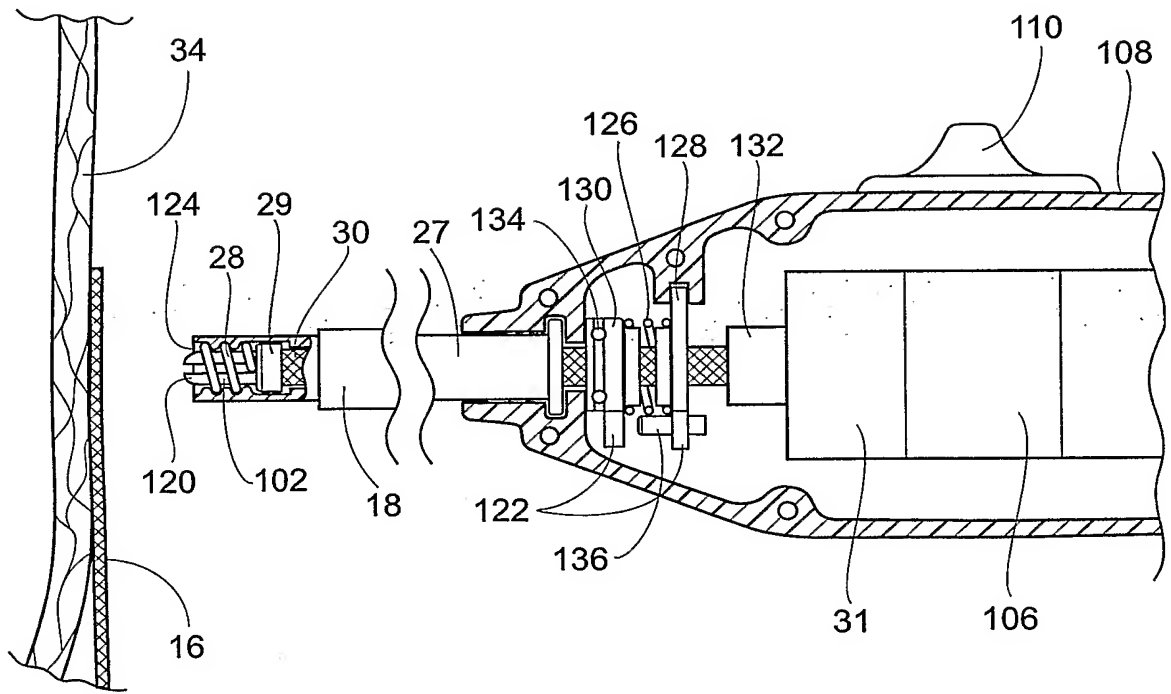


Fig. 22

**Fig. 23**

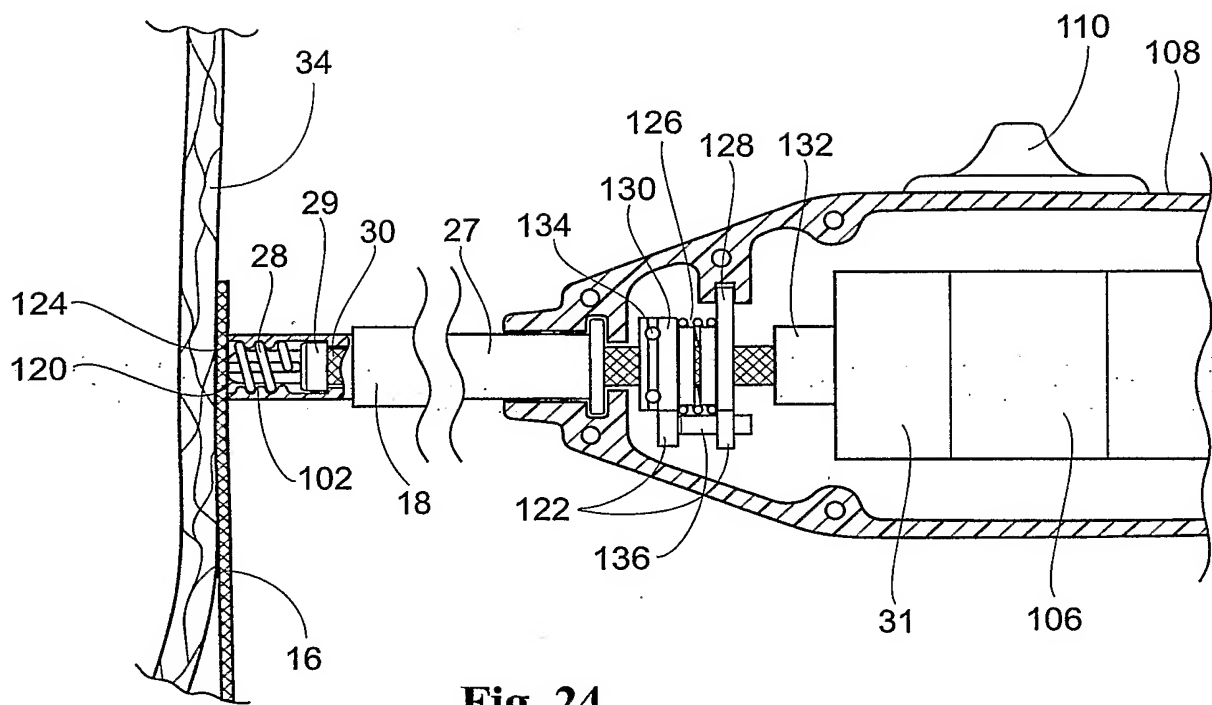


Fig. 24

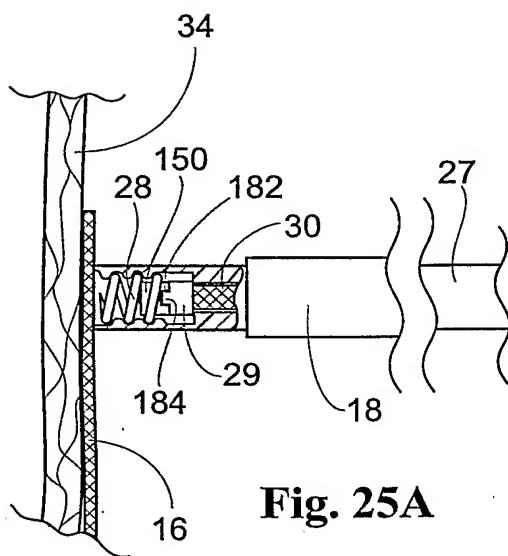


Fig. 25A

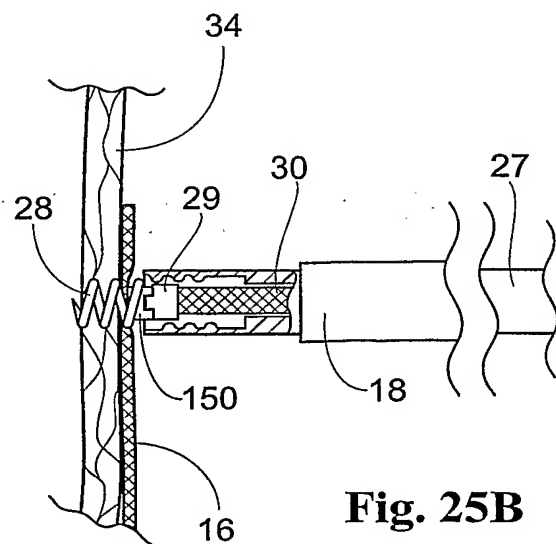


Fig. 25B

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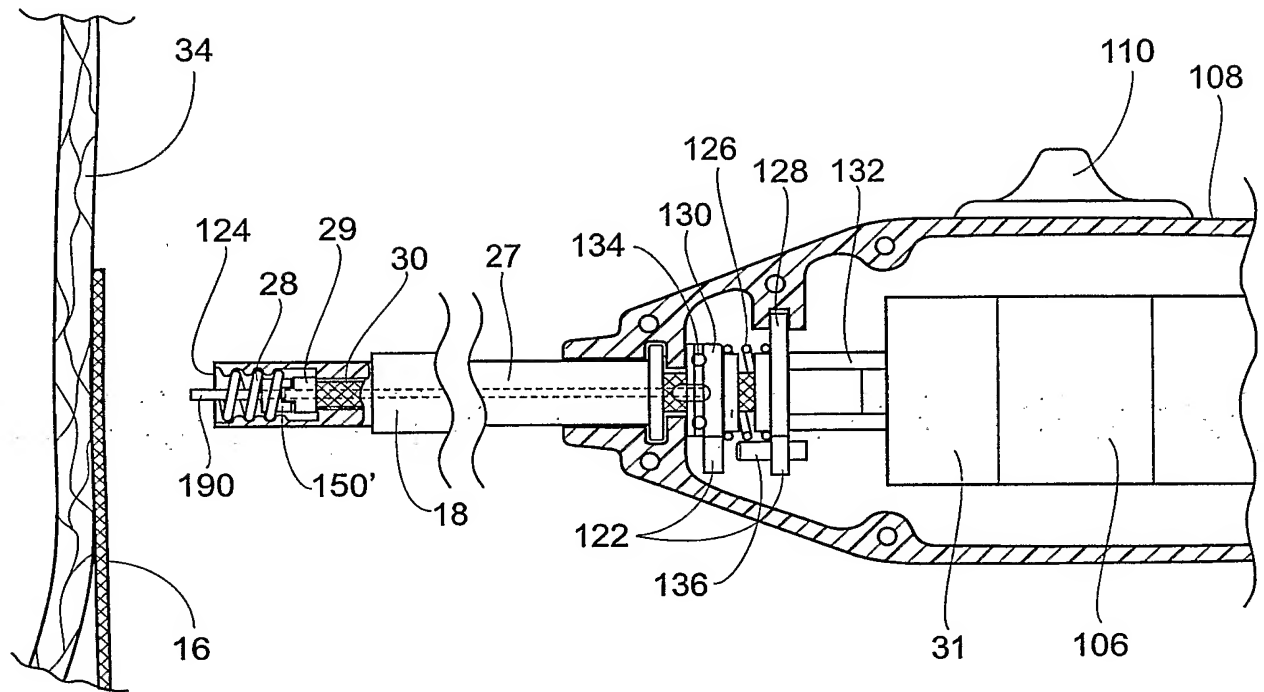


Fig. 26A

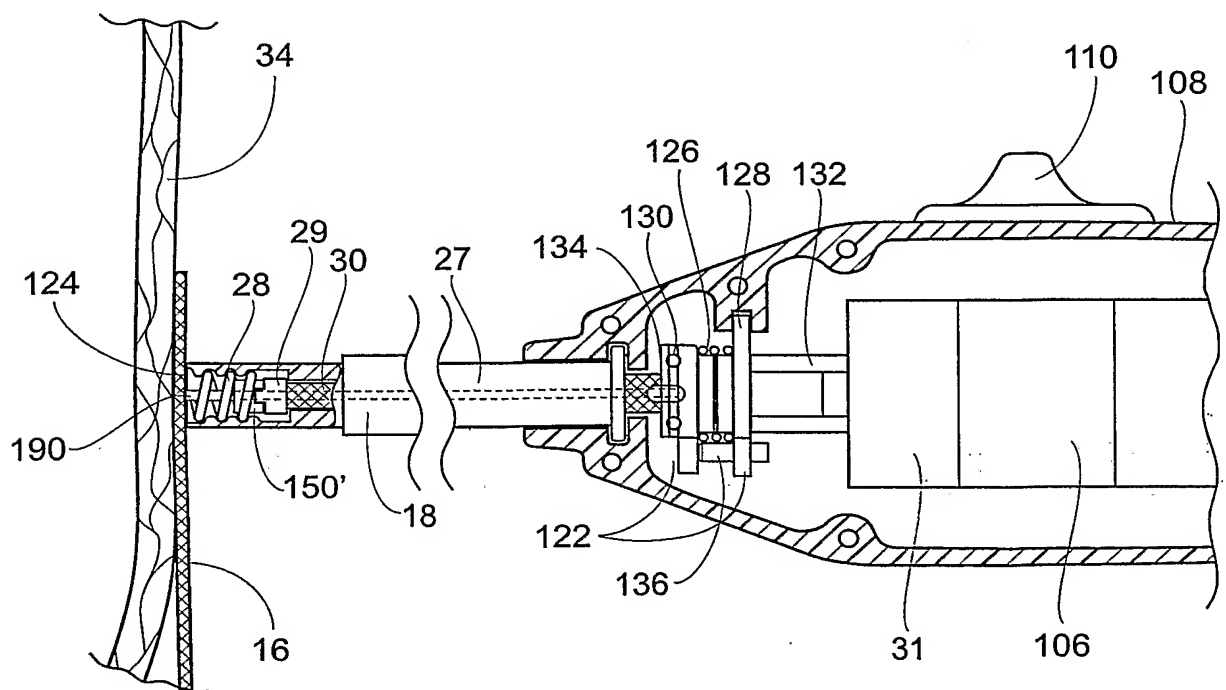


Fig. 26B

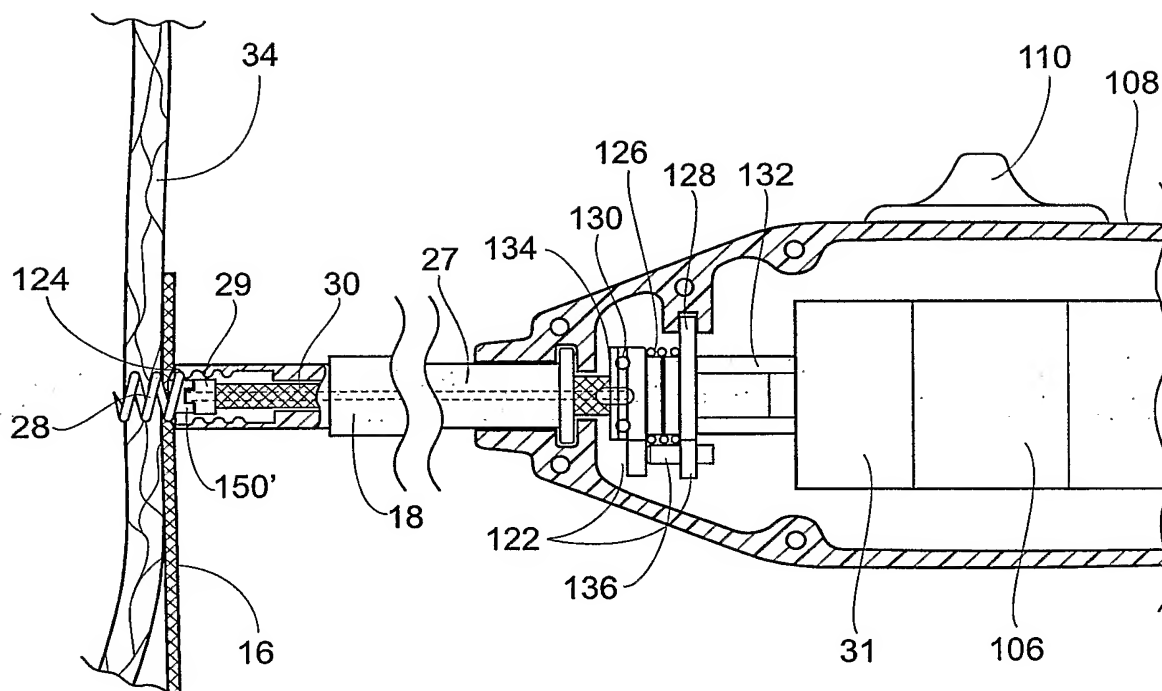


Fig. 26C

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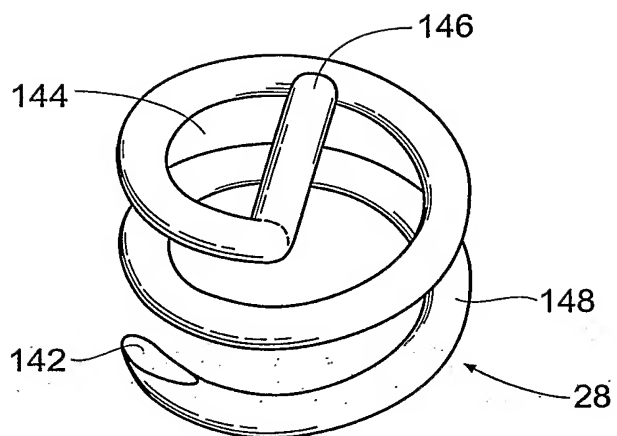


Fig. 27

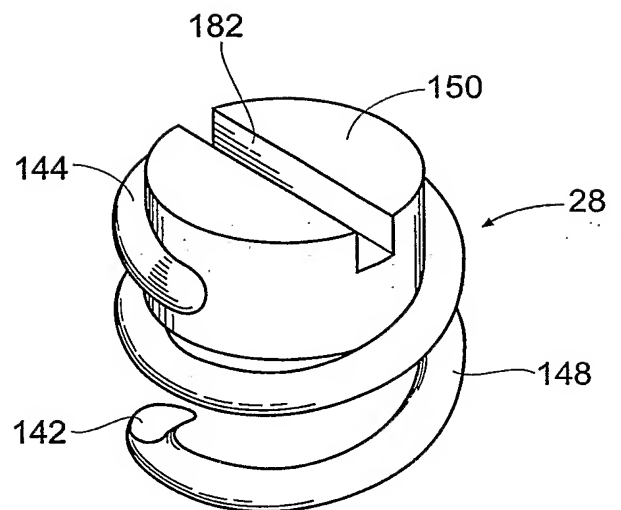


Fig. 28A

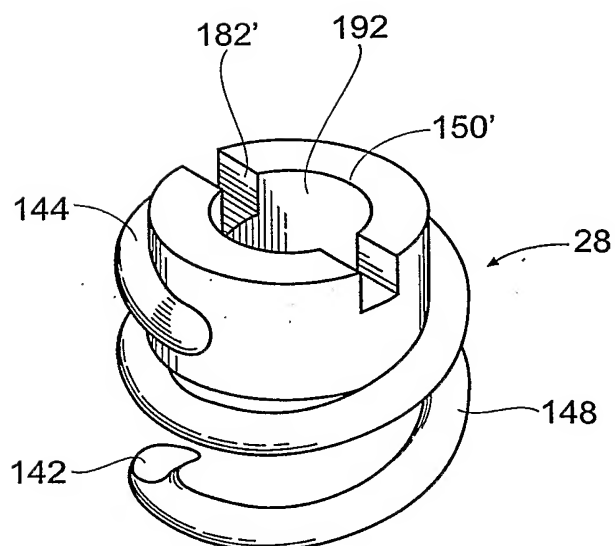
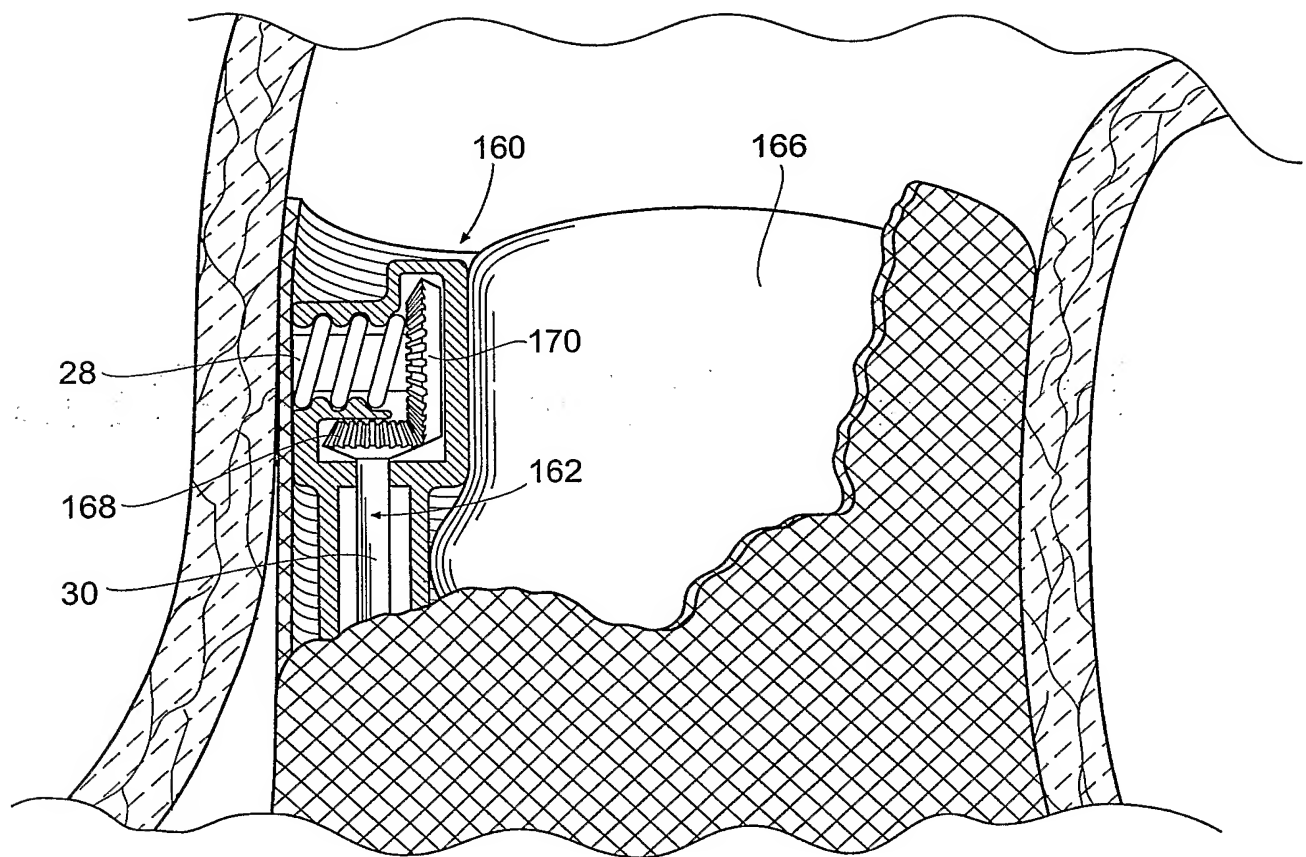


Fig. 28B

**Fig. 29**

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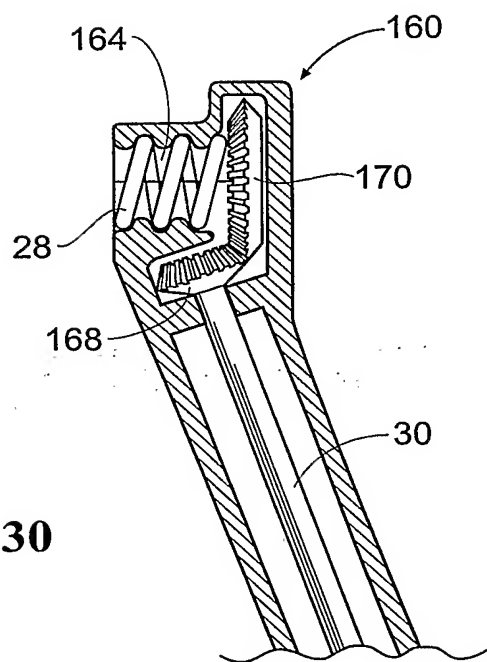


Fig. 30

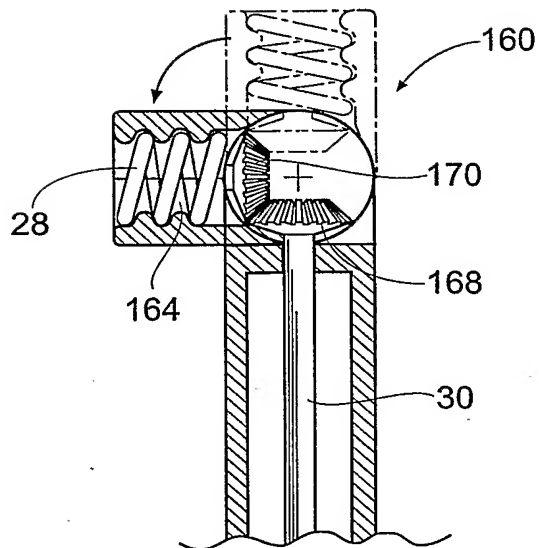


Fig. 31

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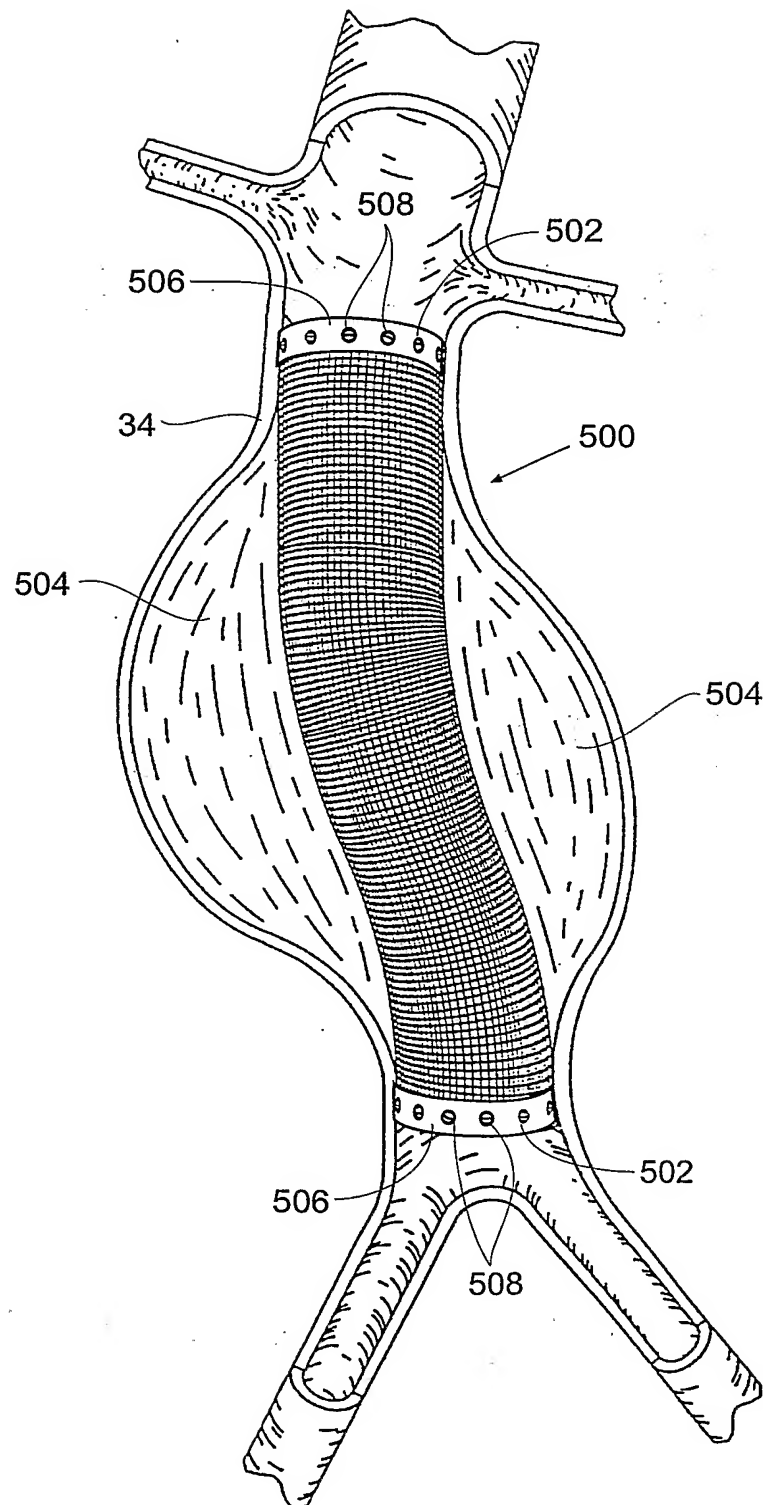
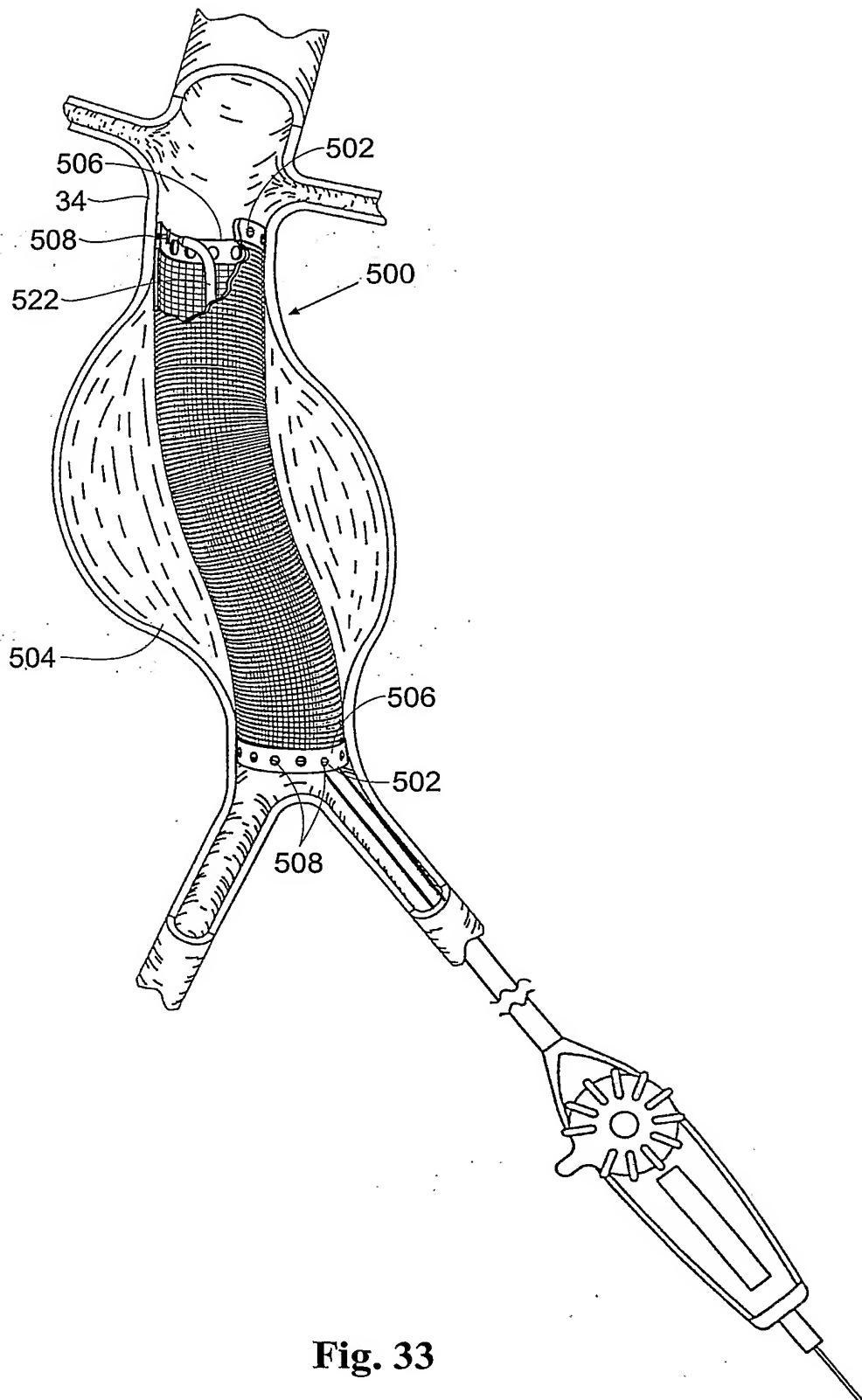


Fig. 32

**Fig. 33**

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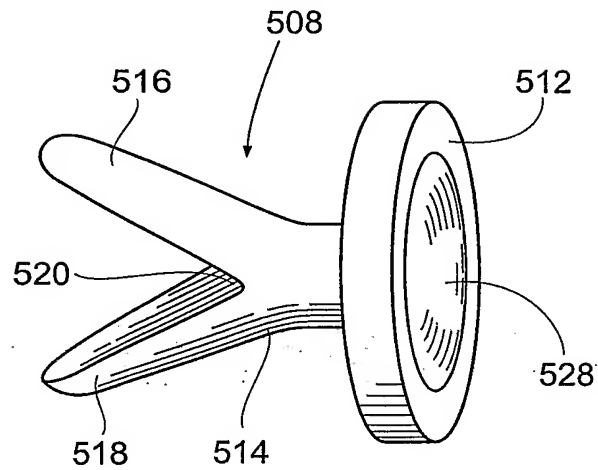


Fig. 34

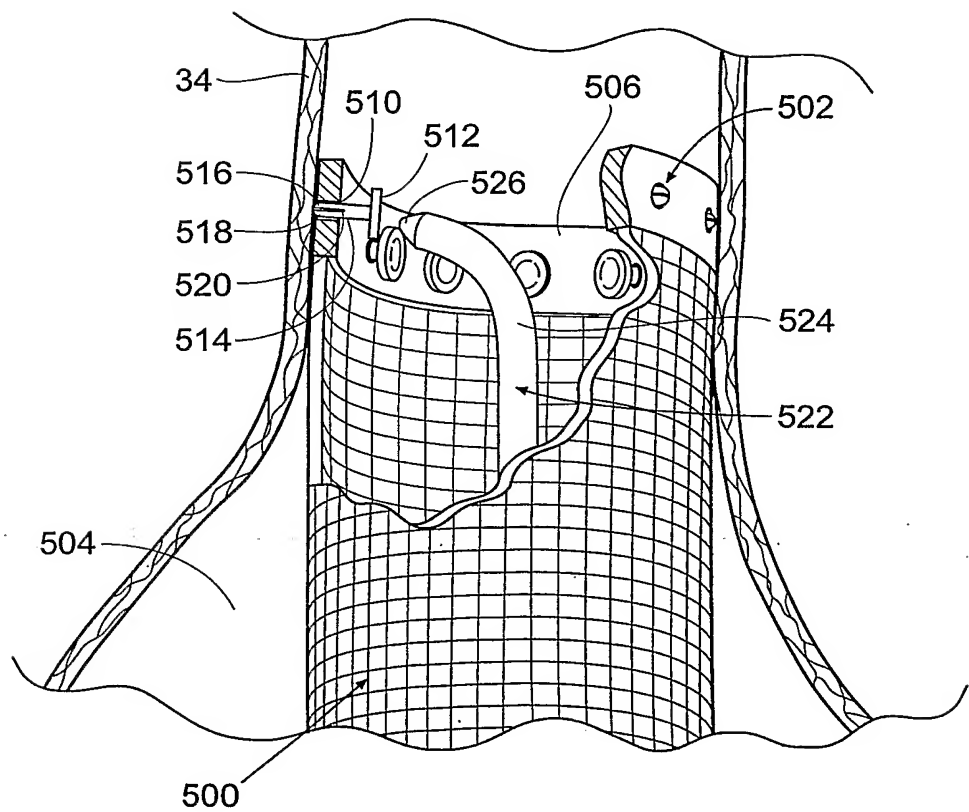
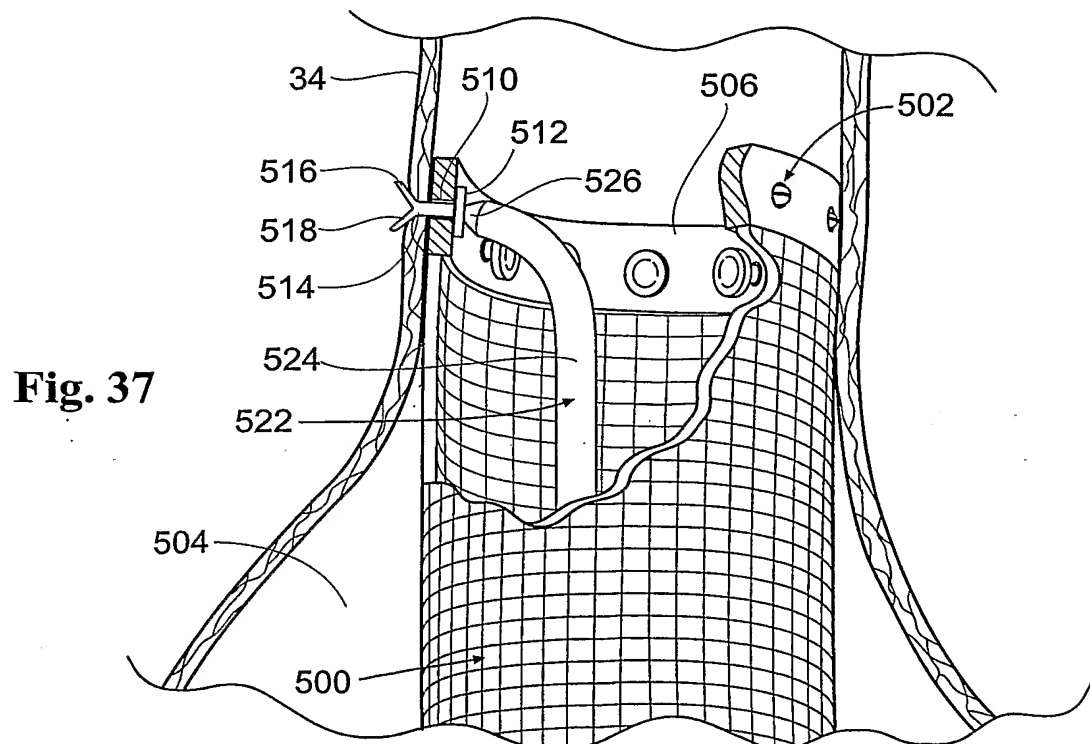
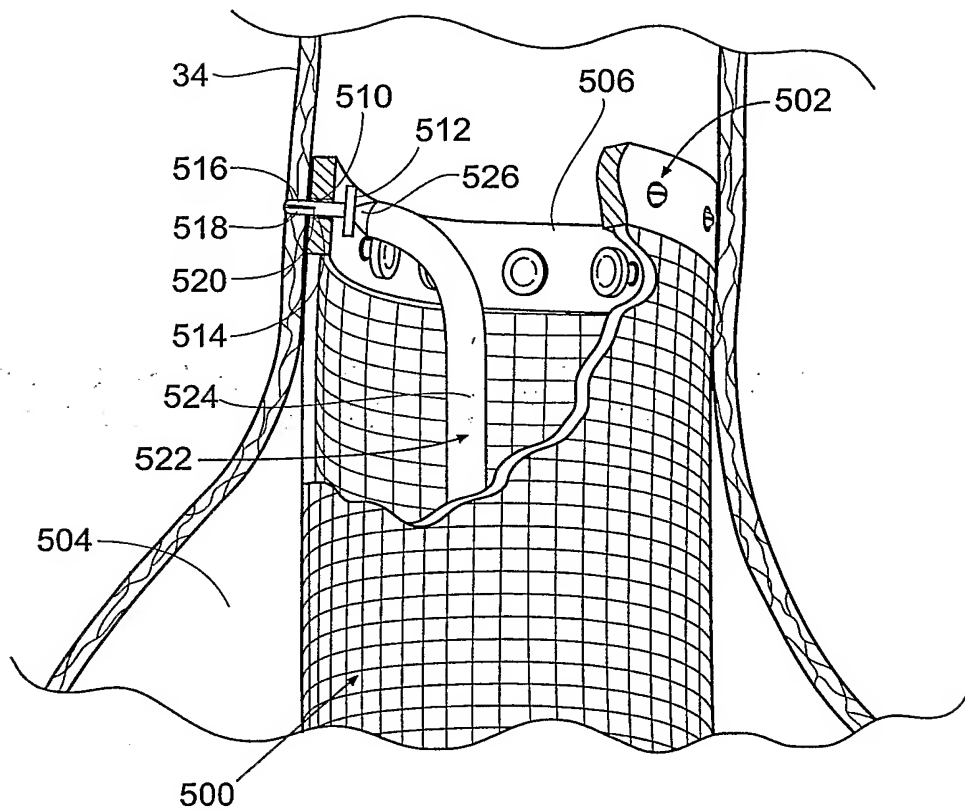


Fig. 35



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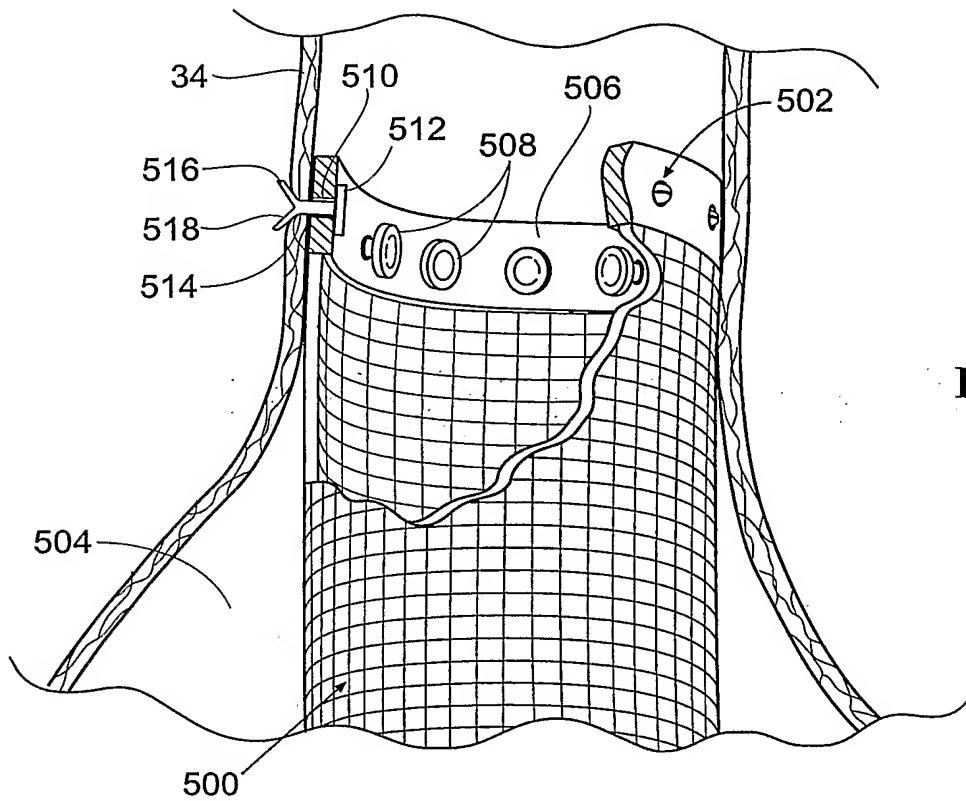


Fig. 38

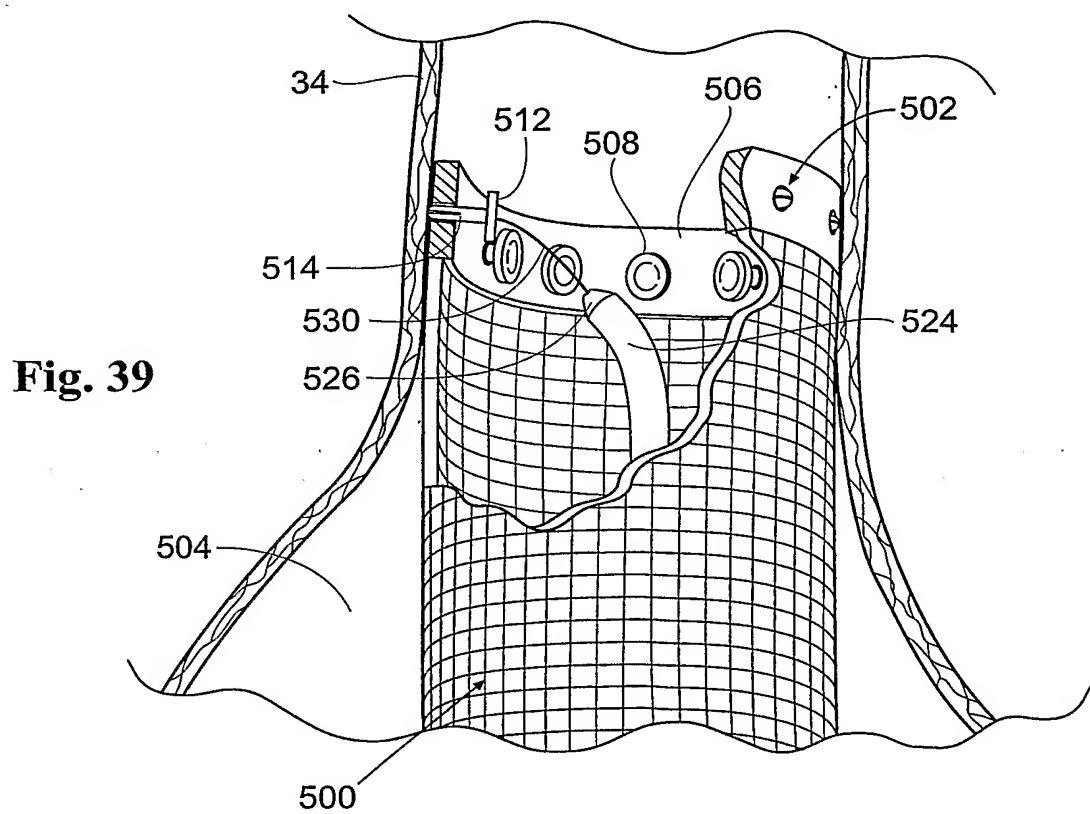
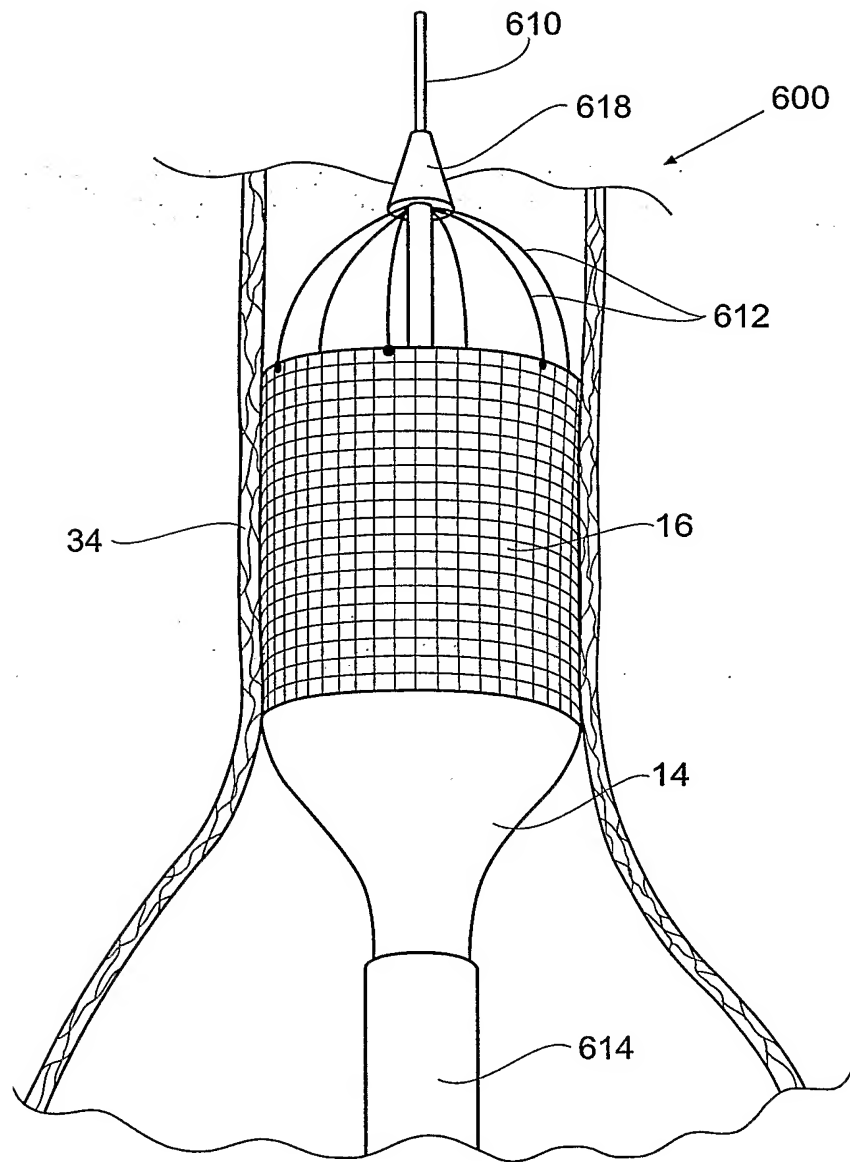
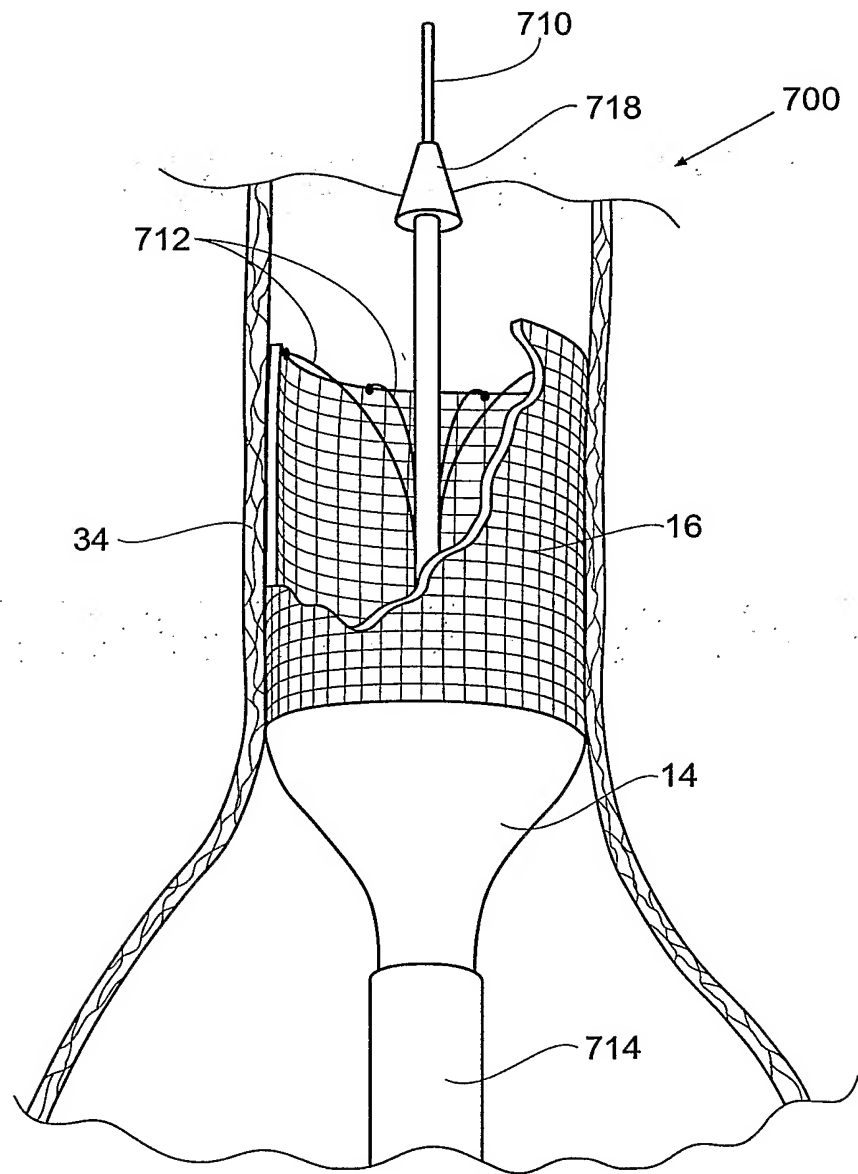


Fig. 39

**Fig. 40**

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**Fig. 41**

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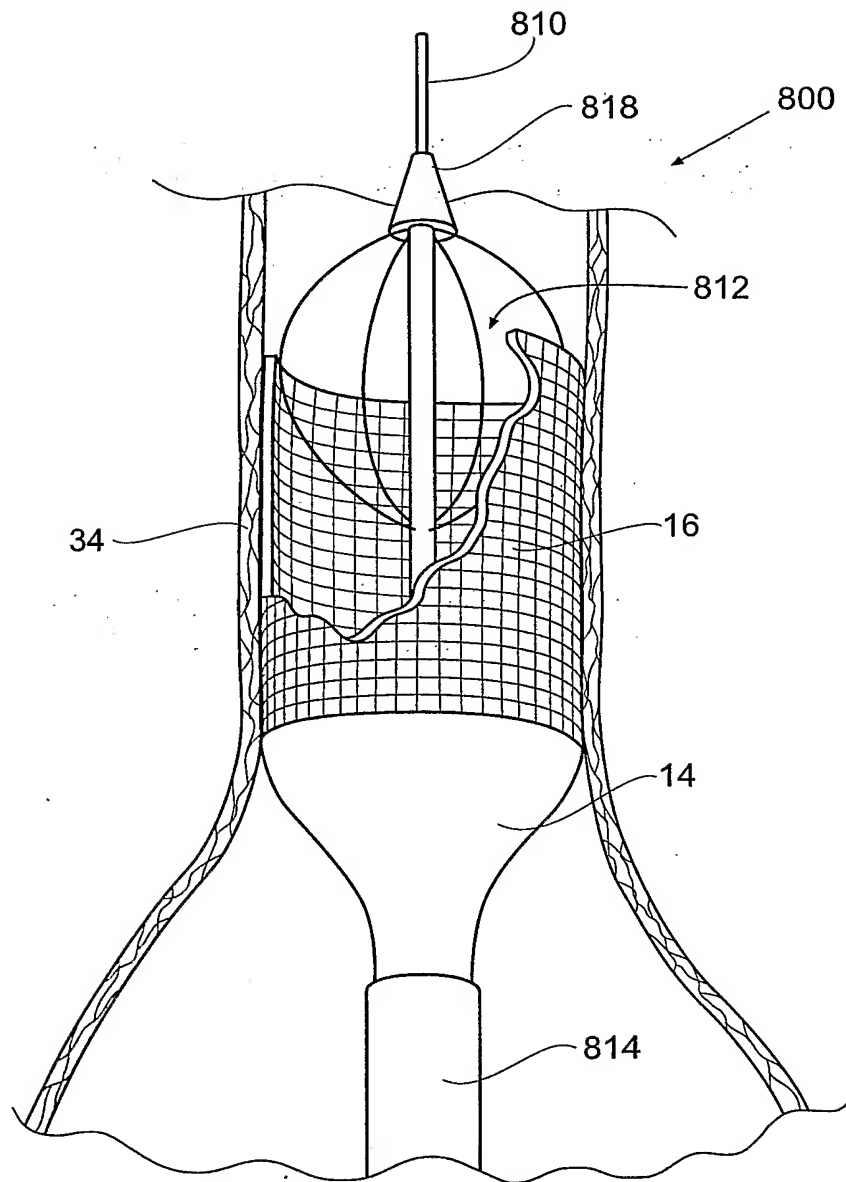


Fig. 42

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
5 June 2003 (05.06.2003)

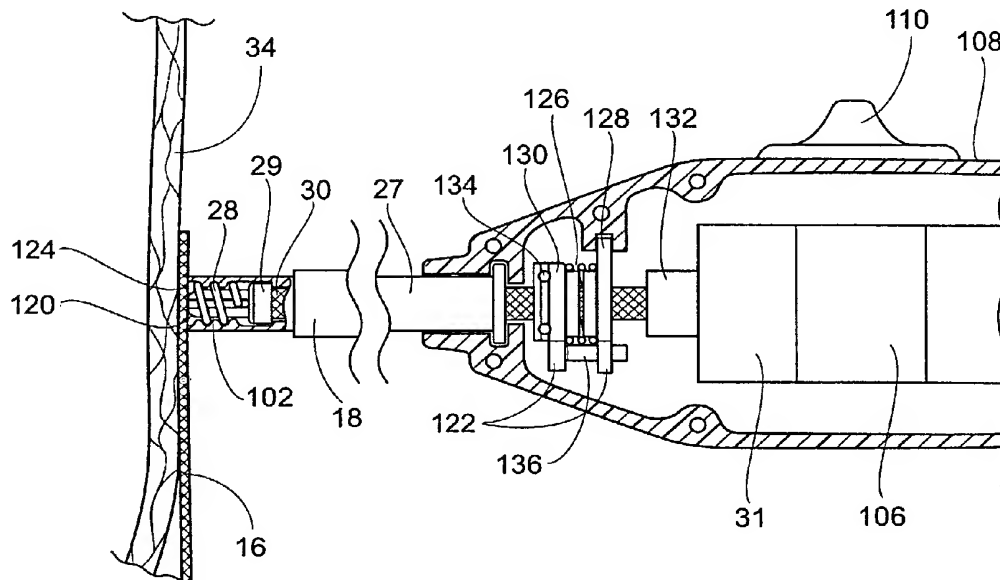
PCT

(10) International Publication Number
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- (21) International Application Number: PCT/US02/38365
- (22) International Filing Date:
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- (71) Applicant: **APTUS ENDOSYSTEMS, INC.** [US/US];
3350 Scott Boulevard, Building 2, Santa Clara, CA 95054 (US).
- (72) Inventors: **BOLDUC, Lee**; 716 Grape Avenue, Sunnyvale, CA 94087 (US). **KAGANOV, Alan, L.**; 190 Cherokee Way, Portola Valley, CA 94028 (US).
- (74) Agents: **RYAN, Daniel, D.** et al.; Post Office Box 26618, Milwaukee, WI 53226 (US).
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— before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments
- (88) Date of publication of the international search report:
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: INTRALUMINAL PROSTHESIS ATTACHMENT SYSTEMS AND METHODS



(57) Abstract: Systems and method implant prostheses in the body. The systems and method provide permanent attachment of the prosthesis in the body. The prosthesis can comprise, e.g., an endovascular graft, which can be deployed without damaging the native blood vessel in either an arterial or a venous system. The endovascular graft can comprise, e.g., a radially expanding vascular stent and/or a stent-graft. The graft can be placed in the vasculature, eg., to exclude or bridge an aneurysm, for example, an abdominal aortic aneurysms. The graft desirably adapts to change in aneurysm morphology and repairs the endovascular aneurysm. The fastening systems (27) and methods can be deployed through the vasculature and manipulated from outside the body, to deliver a fastener (28) to attach the graft to the vessel wall.



WO 03/045467 A3

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US02/38365

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/00

US CL : 606/104

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/72, 73, 99, 104, 142, 151, 153, 232; 81/429, 463, 469, 478, 479; 411/425; 623/1.36

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
Please See Continuation Sheet

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,625,597 A (CAST) 02 December 1986 (01.12.1986), see entire document.	1-8,11-13,22,34-36
Y		9,10
X	US 5,662,683 A (KAY) 02 September 1997 (02.09.1997), see figures 2-7.	22-24
X	US 3,499,222 A (LINKOW et al.) 10 March 1970 (10.03.1970), see figure 17.	22, 25
X	US 5,582,616 A (BOLDUC et al.) 10 December 1996 (10.12.1996), see entire document.	39-41
X	US 5,456,714 A (OWEN) 10 October 1995 (10.10.1995), see entire document.	44



Further documents are listed in the continuation of Box C.



See patent family annex.

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Date of the actual completion of the international search

03 March 2003 (03.03.2003)

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

PCT/US02/38365

C. (Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,626,613 A (SCHMIEDING) 06 May 1997 (06.05.1997), see entire document.	45

INTERNATIONAL SEARCH REPORT

PCT/US02/38365

Continuation of B. FIELDS SEARCHED Item 3:

EAST BRS

search terms: helical, coil, magnetized, fastener, force, sensor, switch, contact, spring, drive, prosthesis

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60/374,833	24 April 2002 (24.04.2002)	US
60/375,807	29 April 2002 (29.04.2002)	US
60/382,084	22 May 2002 (22.05.2002)	US

(71) Applicant: **EVA CORPORATION** [US/US]; Hugh H. Trout, III, M.D., 8218 Wisconsin Avenue, Suite 204, Bethesda, MD 20814 (US).

(72) Inventors: **TROUT, Hugh, H., III**; 8218 Wisconsin Avenue, Suite 204, Bethesda, MD 20814 (US). **PATTERSON, Frank**; 18 Juniper Ridge Road, Exeter, NH 03833 (US).

(74) Agents: **COULBY, John, N.** et al.; Collier Shannon Scott, PLLC, 3050 K Street, N.W., Suite 400, Washington, DC 20007 (US).

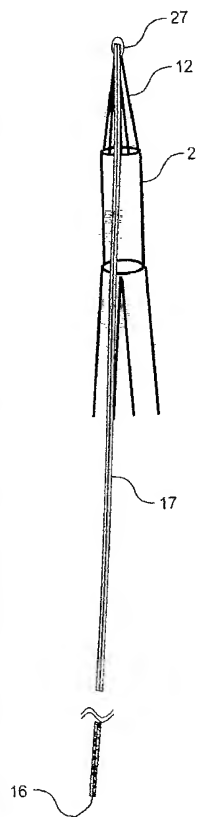
(81) Designated States (*national*): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (*regional*): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

[Continued on next page]

(54) Title: METHOD AND APPARATUS TO ATTACH AN UNSUPPORTED SURGICAL COMPONENT

(57) Abstract: An insertion apparatus comprises an introducer sheath, a surgical component (1), at least two attachment wires (12), and a longitudinal wire (11). The insertion apparatus is used for deploying a surgical component (1) to a site in a vessel. The introducer sheath has a lumen, a proximal opening and a distal opening with an appropriate diameter and length allowing for insertion and navigation through the vessel. The surgical component (1) has a tube portion (2) with a top and at least one limb. The surgical component (1) corresponds to the site in the vessel and fits within the lumen of the introducer sheath. The attachment wires (12) have a first and a second end. The first end is releasably connected to the top of the surgical component (1). The longitudinal wire (11) anchors from the second end extending through the surgical component (1) and through the introducer sheath to the releasing mechanism outside the vessel.



WO 03/079935 A1



Published:

- with international search report
- before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments

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METHOD AND APPARATUS TO ATTACH AN UNSUPPORTED SURGICAL COMPONENT

CROSS-REFERENCE TO RELATED APPLICATIONS

- 5 **[0001]** The present invention relates to, and is entitled to the benefit of the earlier filing date and priority of U.S. Application No. 60/364, 601 filed March 18, 2002, U.S. Application No. 60/382,084, filed May 22, 2002; U.S. Application No. 60/374,833 filed April 24, 2002; and U.S. Application No. 60/375,807 filed April 29, 2002.

FIELD OF THE INVENTION

- 10 **[0002]** The present invention relates to apparatus and methods for performing a surgical procedure. More particularly, the present invention relates to apparatus and methods to attach an unsupported surgical component.

BACKGROUND OF THE INVENTION

- 15 **[0003]** An aneurysm is a ballooning of the wall of an artery resulting from the weakening of the artery due to disease or other conditions. Left untreated, the aneurysm will frequently rupture, resulting in loss of blood through the rupture and death.

- 20 **[0004]** Aortic aneurysms are the most common form of arterial aneurysm and are life threatening. The aorta is the main artery which supplies blood to the circulatory system. The aorta arises from the left ventricle of the heart, passes upward and bends over behind the heart, and passes down through the thorax and abdomen. Among other arterial vessels branching off the aorta along its path, the abdominal aorta supplies two side vessels to the kidneys, the renal arteries. Below the level of the renal arteries, the abdominal aorta continues to about the level of the fourth lumbar vertebrae (or the navel), where it divides into the iliac arteries. The iliac arteries, in turn, supply blood to the lower extremities and perineal region.

- 25 **[0005]** It is common for an aortic aneurysm to occur in that portion of the abdominal aorta between the renal arteries and the iliac arteries. This portion of the abdominal

aorta is particularly susceptible to weakening, resulting in an aortic aneurysm. Such an aneurysm is often located near the iliac arteries. An aortic aneurysm larger than about 5 cm in diameter in this section of the aorta is ominous. Left untreated, the aneurysm may rupture, resulting in rapid, and usually fatal, hemorrhaging. Typically, a surgical procedure is not performed on aneurysms smaller than 5 cm because no statistical benefit exists in performing such procedures.

[0006] Aneurysms in the abdominal aorta are associated with a particularly high mortality rate; accordingly, current medical standards call for urgent operative repair. Abdominal surgery, however, results in substantial stress to the body. Although the mortality rate for an aortic aneurysm is high, there is also considerable mortality and morbidity associated with open surgical intervention to repair an aortic aneurysm. This intervention involves penetrating the abdominal wall to the location of the aneurysm to reinforce or replace the diseased section of the aortic aneurysm. A prosthetic device, typically a synthetic tube graft, is used for this purpose. The graft serves to exclude the aneurysm from the circulatory system, thus relieving pressure and stress on the weakened section of the aorta at the aneurysm.

[0007] Repair of an aortic aneurysm by surgical means is a major operative procedure. Substantial morbidity accompanies the procedure, resulting in a protracted recovery period. Further, the procedure entails a substantial risk of mortality. While surgical intervention may be indicated and the surgery carries attendant risk, certain patients may not be able to tolerate the stress of intra-abdominal surgery. It is, therefore, desirable to reduce the mortality and morbidity associated with intra-abdominal surgical intervention.

[0008] In recent years, methods have been developed to attempt to treat an aortic aneurysm without the attendant risks of intra-abdominal surgical intervention. Among them are inventions disclosed and claimed in Kornberg, U.S. Patent No. 4,562,596 for Aortic Graft, Device and Method for Performing an Intraluminal Abdominal Aortic Aneurysm Repair; Lazarus, U.S. Patent No. 4,787,899 for Intraluminal Graft Device, System and Method; and Taheri, U.S. Patent No. 5,042,707 for Intravascular Stapler, and Method of Operating Same.

[0009] Although in recent years certain techniques have been developed that may reduce the stress, morbidity, and risk of mortality associated with surgical intervention to

repair aortic aneurysms, none of the systems that have been developed effectively treat the aneurysm and exclude the affected section of aorta from the pressures and stresses associated with circulation. None of the devices disclosed in the references provide a reliable and quick means to reinforce an aneurysmal artery. In addition, all of the prior references require a sufficiently large section of healthy aorta surrounding the aneurysm to ensure attachment of the graft. The neck of the aorta at the cephalad end (i.e., above the aneurysm) is usually sufficient to maintain a graft's attachment means. However, when an aneurysm is located near the iliac arteries, there may be an ill-defined neck or no neck below the aneurysm. Such an ill-defined neck would have an insufficient amount of healthy aortic tissue to which to successfully mount a graft. Furthermore, much of the abdominal aorta wall may be calcified which may make it extremely difficult to attach the graft to the wall. Furthermore, the prior art does not disclose surgical devices that can be used during a surgical procedure that address these concerns. Others have developed devices that are not easily manipulated or oriented during intraluminal surgical procedures.

[0010] It is therefore an advantage of some, but not necessarily all, embodiments of the present invention to provide an improved apparatus and method to attach an unsupported surgical component.

[0011] Additional advantages of various embodiments of the invention are set forth, in part, in the description that follows and, in part, will be apparent to one of ordinary skill in the art from the description and/or from the practice of the invention.

SUMMARY OF THE INVENTION

[0012] Responsive to the foregoing challenges, Applicant has developed an innovative method and apparatus to attach an unsupported surgical component.

[0013] An embodiment of the present invention is an insertion apparatus for deploying a surgical component to a site in a vessel comprising: attachment means for attaching the surgical component to the insertion apparatus, wherein the attachment means is releasably connected to the surgical component; and release means for releasing the attachment means from the surgical component, wherein the release means is in communication with the attachment means.

[0014] An embodiment of the present invention is an insertion apparatus for deploying a surgical component to a site in a vessel comprising: at least one

attachment wire with a first end and a second end; a support wire; wherein the first end of the at least one attachment wire is releasably connected to the surgical component and the second end is connected to the support wire; and wherein the attachment wire and support wire positions the surgical component at a site in the vessel.

5 **[0015]** An embodiment of the present invention is an insertion apparatus for deploying a surgical component to a site in a vessel comprising: an attachment hoop releasably connected to the surgical component; at least one attachment wire with a first end and a second end; a support wire; wherein the first end of the at least one attachment wire is connected to the attachment hoop and the second end of the at least one attachment wire is connected to the support wire; and wherein the insertion
10 apparatus positions the surgical component in the vessel.

[0016] An embodiment of the present invention is an insertion system for deploying a surgical component to a site in a vessel comprising: a surgical component; an insertion apparatus; attachment means for attaching the surgical component to the insertion
15 apparatus, wherein the attachment means is releasably connected to the surgical component; and release means for releasing the attachment means from the surgical component, wherein the release means is in communication with the attachment means.

[0017] An embodiment of the present invention is a method for positioning a surgical
20 component to a site in a vessel comprising the steps of: introducing an insertion apparatus proximal to the site in the vessel; activating the insertion apparatus; and withdrawing the insertion apparatus. An embodiment of the present invention further comprises the step of fastening the surgical component to the vessel.

[0018] In accordance with an embodiment of the present invention, there is provided
25 an introducer sheath for deploying a surgical component to a site in a vessel. The apparatus includes an introducer sheath, a surgical component, at least two attachment wires, and a longitudinal wire. The introducer sheath has a lumen, a proximal opening and a distal opening with an appropriate diameter and length allowing for insertion and navigation through the vessel. The surgical component has a tube portion with a top
30 and at least one limb. The surgical component corresponds to the site in the vessel and fits within the lumen of the introducer sheath. The attachment wires have a first and a second end. The first end is releasably connected to the top of the surgical component

and the second end converges above the top of the surgical component. The activation of a releasing mechanism releases the first end from the top of the surgical component.

The longitudinal wire anchors from the second end extending through the surgical component and through the introducer sheath to the releasing mechanism outside the

vessel.

[0019] In accordance with an embodiment of the present invention, there is provided a method for attaching a surgical component with an insertion apparatus to site in a vessel comprising the steps of: inserting the insertion apparatus to the site in the vessel; positioning the surgical component to the site in the vessel; fastening the surgical component to the vessel; activating a release mechanism of the insertion apparatus; and withdrawing the insertion apparatus.

[0020] It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only, and are not restrictive of the invention as claimed. The accompanying drawings, which are incorporated herein by reference, and which constitute a part of this specification, illustrate certain embodiments of the invention and, together with the detailed description, serve to explain the principles of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] In order to assist the understanding of this invention, reference will now be made to the appended drawings, in which like reference characters refer to like elements. The drawings are exemplary only, and should not be construed as limiting the invention.

[0022] Figs. 1 and 2 are perspective views of a surgical component with and without distinctive markings according to an embodiment of the present invention.

[0023] Fig. 3 is a perspective view of a surgical component according to an embodiment of the present invention.

[0024] Figs. 4, 5, and 6 are enlarged perspective views of embodiments of a release mechanism according to embodiments of the present invention.

[0025] Fig. 7 is a perspective view of an embodiment of the attachment wires secured to a bulb with a subsequent device attached thereto.

[0026] Fig. 8 is a perspective view of an expanded surgical component with an insulated longitudinal wire according to an embodiment of the present invention.

[0027] Fig. 9 is a perspective view of a contracted surgical component according to an embodiment of the present invention.

[0028] Fig. 10 is a perspective view of an embodiment of the surgical component attached to a release mechanism employing an electrical current to separate the attachment wires.

[0029] Fig. 11 is a perspective view of an embodiment of the surgical component having distinctive markings and sutures attached to the ends of the limbs.

[0030] Figs. 12 and 13 are perspective views of the graft packed with a short sheath, which may be flared according to an embodiment of the present invention.

[0031] Figs. 14, 15, and 16 are perspective views of the graft with limbs trimmed to an appropriate length by the inserter to accommodate patient size according to an embodiment of the present invention.

[0032] Figs. 17 and 18 are perspective views of the introducer sheath with a detachable hemostatic valve and a dilator according to an embodiment of the present invention.

[0033] Fig. 19 is a perspective view of introducer sheath and the short sheath wherein the short sheath containing the graft is introduced into the introducer sheath according to an embodiment of the present invention.

[0034] Fig. 20 is a perspective view of the graft advanced to the area just before the soft area of the introducer sheath where the graft is entirely removed from the short sheath according to an embodiment of the present invention.

[0035] Figs. 21 and 22 are perspective views of the graft with the short sheath removed and the expansion of the soft or resilient area according to an embodiment of the present invention.

[0036] Fig. 23 is a perspective view of the graft advanced to the end of the introducer sheath according to an embodiment of the present invention.

[0037] Figs. 24 and 25 are perspective views of a long delivery catheter and a short sheath with a graft according to an embodiment of the present invention.

[0038] Figs. 26 and 27 are perspective views of the top of the short sheath being placed at the opening of the long delivery catheter according to an embodiment of the present invention.

[0039] Fig. 28 is a perspective view of the entire graft assembly advanced into the

long delivery catheter according to an embodiment of the present invention.

[0040] Fig. 29 is a perspective view of an embodiment of the insertion apparatus within an aneurysm.

[0041] Figs. 30 and 31 are perspective views of an embodiment of the insertion apparatus with a snare catheter within an aneurysm.

[0042] Figs. 32 and 33 are perspective views of the introducer sheath pulled back from the graft in the aneurysm according to an embodiment of the present invention.

[0043] Fig. 34 is a perspective view of the unsupported graft within the aortic neck with the attachment wires unrestrained according to an embodiment of the present invention.

[0044] Fig. 35 is a perspective view of the snare catheter passed through the left femoral artery out to the right femoral artery according to an embodiment of the present invention.

[0045] Figs. 36 and 37 are perspective views of the aneurysm with graft limbs in the right femoral artery and the left femoral artery according to an embodiment of the present invention.

[0046] Fig. 38 is a perspective view of a fastener delivery catheter inserted and positioned within the graft located in the aortic neck according to an embodiment of the present invention.

[0047] Fig. 39 is a perspective view of the graft with fasteners inserted around the top portion of the graft according to an embodiment of the present invention.

[0048] Figs. 40 and 41 are perspective views releasing the attachment wires from a graft with the fasteners inserted according to an embodiment of the present invention.

[0049] Fig. 42 is a perspective view of the snare catheter inserted above the attachment wires according to an embodiment of the present invention.

[0050] Figs. 43 and 44 are perspective views of the snare catheter tightened around the attachment wires for removal according to an embodiment of the present invention.

[0051] Fig. 45 is a perspective view of the graft in the aneurysm without the attachment wires according to an embodiment of the present invention.

[0052] Fig. 46 is a perspective view of two stents inserted in the right and left limbs of the graft according to an embodiment of the present invention.

[0053] Fig. 47 is a perspective view of the sutures attached to the right and left limbs

of the graft which have been cut by a suture cutter according to an embodiment of the present invention.

[0054] Fig. 48 is a perspective view of an embodiment of the longitudinal wire with a containment sheath according to an embodiment of the present invention.

5 **[0055]** Fig. 49 is a perspective view of the containment sheath enclosing the attachment wires of the graft according to an embodiment of the present invention.

[0056] Fig. 50 is a perspective view of an alternate embodiment of the short sheath with an open or partial sheath attached according to an embodiment of the present invention.

10 **[0057]** Fig. 51 is a perspective view of an insertion sheath with a short sheath according to an embodiment of the present invention.

[0058] Fig. 52 is a perspective view of an alternate embodiment of the short sheath with a closed circumferential sheath according to an embodiment of the present invention.

15 **[0059]** Figs. 53 and 54 are perspective views of the graft when a release mechanism is applied according to an embodiment of the present invention.

[0060] Figs. 55 and 56 are perspective views of the constraining and releasing of the attachment wires according to an embodiment of the present invention.

20 **[0061]** Fig. 57 is a perspective view of a method to attach and detach the tube portion of the graft from the attachment wires according to an embodiment of the present invention.

[0062] Fig. 58 is a perspective view of the tube portion of a graft contained within the circumferential short sheath according to an embodiment of the present invention.

25 **[0063]** Fig. 59 is a perspective view of the introducer sheath having a plurality of soft resilient areas and a hemostatic valve according to an embodiment of the present invention.

[0064] Fig. 60 is a perspective view of introducer sheaths having a variety of connectors and hemostatic valves according to an embodiment of the present invention.

30 **[0065]** Fig. 61 is a perspective view of multiple ports within the inner wall of the introducer sheath according to an embodiment of the present invention.

[0066] Fig. 62 is a cross section view of the introducer sheath with a passageway according to an embodiment of the present invention.

[0067] Fig. 63 is a perspective view of an introducer sheath containing a plurality of soft spots attached by a connector to a double port also having a plurality of soft spots according to an embodiment of the present invention.

[0068] Fig. 64 is a perspective view of the introducer sheath having a user-controlled variable restricting device according to an embodiment of the present invention.

[0069] Figs. 65 and 66 are perspective views of a suture cutter with a suture according to an embodiment of the present invention.

[0070] Fig. 67 is a perspective view of an embodiment of a closed circumferential sheath with a partial or open sheath according to an embodiment of the present invention.

DETAILED DESCRIPTION OF EMBODIMENTS OF THE INVENTION

[0071] Reference will now be made in detail to embodiments of the present invention, examples of which are illustrated in the accompanying drawings.

[0072] The following methods and apparatus may be used with any suitable surgical components. By way of example only, the following paragraphs describe methods of use and the apparatus with surgical components, such as, but not limited to, grafts, prosthetic grafts, endografts, patches, or any other suitable surgical component. For purposes of explanation only, these surgical components may be on-the-shelf ready for use or custom fabricated. The surgical components may have the tube portion **2**, as shown in Fig. 1, with fixed length. The surgical component may be a patch or tubular in shape, and may or may not have limbs. If a custom made surgical component were required, it is likely to be in an unusual circumstance and that would be known in advance (because of the preoperative three dimensional (3D) computerized tomography (CT) scan or any other appropriate scan or modality) and a special order could be placed. The following examples are explanatory only and not meant to be limiting of the type of surgical component that may be used.

[0073] Fig. 1 depicts a surgical component **1**, which may be, for purposes of example only, and is not limited to, a prosthetic bifurcated graft **1**. This surgical component may have a fixed length tube portion **2** of any suitable size and may be, but is not limited to, from about 1-10cm and may be comprised of, but is not limited to, Dacron, polyester, or PTFE. Graft limbs **3** and **4** may be supplied along with the intent that they will be trimmed to fit the patient size.

[0074] Depending on the size of the vessel in the patient, each tube diameter may be supplied with three different limb diameters. For example, the middle diameter may be one half of the tube diameter and the two others may be about 2mm less and about 2mm more than half the diameter of the tube portion. Thus, a 20mm tube may come in three versions: 1) 20mm tube and 8mm limb diameter; 2) 20mm tube and 10mm limb diameter; and 3) 20mm tube and 12mm limb diameter. It is also possible to have one limb diameter larger than the other.

[0075] In Fig. 2, distinctive markings depicted by rings, dots and dashes may be added to the graft. Distinctive markings may be comprised of radiopaque markers or any other suitable distinctive markings, radiopaque or not, to facilitate easy identification under imaging techniques, including, but not limited to, fluoroscopy, magnetic resonance (MR), or any other suitable imaging modality. Radiopaque markers with surgical components are described in U.S. Application No. 10/173,028 filed June 18, 2001, the entire disclosure and subject matter of which is hereby incorporated herein by reference. These markers may be small pieces of radiopaque material or may be vaporized radiopaque material imbedded into the graft material, or of any other suitable material and affixed by any other suitable method. These markers will allow the inserter to locate the top **5**, the bifurcation **6**, and the ends of the limbs **7** and **8**. These markers will also enable the inserter to distinguish among the medial **9** and lateral **10** portions of the graft limbs.

[0076] In Fig. 3, attachment means may comprise a support wire **11**, attachment wire **12**, and may further comprise additional support structures, including, but not limited to, at least one ring or hoop structure. Support wire **11** may have a slight bend or a tip deflection capability and may be inserted through the left **4** or right **3** limb of the graft **1** up through the tube portion **2** of the graft **1**. The support wire **11** may be insulated. In Figs. 3-6, a plurality of attachment wires **12** are connected to the graft **1** and to the support wire **11**, either directly or through an intermediate structure, such as, but not limited to, a ring or hoop, described in more detail below. The attachment wires **12** may be connected to the top **5** of the graft **1** shown in Fig. 2.

[0077] Details of the attachment wires **12** are shown in three blow-up drawings, Figs. 4, 5, and 6. In one embodiment, an electric current is applied to the attachment wires

12. Attachment wires **12** connect to a filament **13** and/or a ball **15** that increases in temperature when a current is supplied. The filament **13** heats and burns through the suture **14** releasing the attachment wires from the graft **3**. Release means may comprise an electrical current, heat, vibration, laser, dissolvable sutures, adhesive, metal alloys, or any other suitable release mechanism. In the embodiment shown in Figs. 4 and 5, the suture **14** is cut by the hot filament **13** and separates from the ball **15**.

Because of the method used to tie the sutures, suture fragments are discouraged from embolizing elsewhere. Fig. 6 depicts another embodiment of the release mechanism where the attachment wires **12** are insulated with any suitable material **68**. When a current is applied to the insulated **68** attachment wires **12**, the filament **13** burns and severs the suture **14** attached to the top **5** of the graft **1**. An exposed portion of the filament **13** may be used to ground the wire through tissue, such as the aortic wall. Multiple different circuit designs may be selected. For instance, instead of using a patient ground (electrical return path), the ground can be provided with a separate conductor onboard the device. Additionally, a feedback circuit, or any other suitable means, may be added to indicate to the user when the separation had been successfully completed.

[0078] A knot **16** of the suture **14** may be placed above the graft to decrease the bulkiness of the graft especially as the graft is being pushed/pulled through the introducer sheath **95**. The balls **15** located near the top **5** of the graft **1** can be at different levels in order to reduce the bulk in any one transverse plane. Moreover, this method of attachment/release can be used in holding and detaching any foreign material in any vessel, artery or vein or in any tissue where a suture is a temporary attachment mechanism. A similar release mechanism could be achieved with magnets, glues that dissolve upon electrical or heat stimulation, or metal alloys that separate in response to heat or electrical current, or any other suitable method.

[0079] It will be apparent to those skilled in the art that variations and modifications of the present invention can be made without departing from the scope or spirit of the invention. For instance, as the need to insert objects into body orifices (whether percutaneously, through small incisions, or endoscopically) increases, it is progressively more important to reduce the size of these objects during their insertion as much as

possible. One way to accomplish this objective is to insert components of the object through a small opening into the area where they will be attached or deployed. Once the components are inserted they may then be attached to each other to form a larger object. This may be accomplished via a scope or sheath inserted into an open orifice, such as, but not limited to, the trachea, the esophagus, the anus, the nose, the vagina or the urethra. Likewise, it may be done through an incision or skin penetration into the chest, abdomen, soft tissue, or a joint. It also may be accomplished through an incision or percutaneous penetration into an artery or vein remote from the desired site of implantation.

[0080] As an example of such an approach, an embodiment shown in Fig. 7, a very fine support wire **11**, which may be, but is not limited to, a wire, a flexible suture, or any other suitable object is attached to a bulb **27** to which attachment wires **12** are connected on one end, on the other, to a graft **1** or the tube portion **2**, such as, but not limited to, a prosthetic graft. This entire device may be compressed and delivered into an aorta through a small catheter. The wire **11** may have a smaller diameter so as to reduce the size of the device as it is being inserted. It may be necessary, however, for the device to be manipulated in such a way that the smaller diameter wire **11** is not capable of facilitating. In such an instance, it may be desirable to introduce over, about, or adjacent to the wire **11** at the distal end **16** a subsequent device **17** that attaches to a part of the bulb **27** so as to provide capabilities not provided by the small diameter wire **11**. For instance, the subsequent device **17** may provide more support for the device, insulation for the wire **68** as in Fig. 8, or some sort of manipulating system that allows torsion or positioning control or control of the angulation of the attachment wires **12** from an expanded configuration in Fig. 7 to a contracted configuration in Fig. 9, or for any other suitable purpose. The subsequent device **17** may be attached to the support wire **11** and/or the bulb **27** by any suitable mechanism for attachment, such as, but not limited to, a snap-on mechanism, magnet, male/female type connector, screw-in attachment, or twist-lock mechanism. Further, the wire **11** with the subsequent device **17** may be disassembled, as desired, by any suitable release mechanism, such as, but not limited to, a switch, lever, heat, magnet, current applied, or current located to a control handle.

[0081] In addition, Fig. 10 depicts in another embodiment a mechanism to separate the attachment wires **12** from the prosthetic graft **1**. An electrical current is applied to insulated **68** wires **11**. In an embodiment, a high resistance connection **18** may then separate the attachment wires **12** from a thin wire or suture **19** disposed at or near the graft **1**. For example, the connector **18** may be a metal alloy that weakens/separates when subjected to a current or it may be a filament that heats and severs an adjacent suture or some other such connector element that allows separation when a current is applied. Fig. 10 depicts a bipolar approach, but a monopolar mechanism with the ground being an adjacent arterial wall is also considered within the scope of the present invention. Thus, it is intended that the present invention cover all such modifications and variations of the invention, provided they come within the scope of the appended claims and their equivalents.

[0082] As shown in Fig. 11, a further embodiment includes a plurality of sutures **14** added to the end portions of the limbs **7** and **8**. The sutures **14** may be attached to identification tags **21**. The sutures **14** may also be removed when the limbs are trimmed to the appropriate length, at which time they may be replaced. The sutures **14** may be included in the packaged graft in order to provide a certainty as to the identification of the right **3** and left **4** limbs as well as the medial **9** and lateral **10** portions of the limb.

[0083] As depicted in Figs. 12 and 13, the graft **1** may be packed in a short sheath **25**. In an embodiment, the short sheath **25** may be flared at the bottom **26**, as shown in Fig. 12. In Figs. 11, 12, and 13, the support wire **11** may be attached to the attachment wires **12** at bulb **27**. In Fig. 5, the attachment wires **12** may be attached to the filament balls **15** that, in turn, are attached to sutures **14** that, in turn, are attached to the top **5** of the tube portion of the graft **1**. This arrangement allows for the bulk of the bulb **27** of the support wire **11**, the attachment wires **12**, the filament ball **15** in Fig 5 and the knots **16** in Fig 5 to be above the top of the graft as the graft is placed within one or more sheaths. The ball **15** is located at or near the tube portion **2** of the graft **1** whereas the bulb **27** is located above the tube portion **2** securing the attachment wires **12**. The ball or bulb **15** or **27** can be the same structural element or may be different to accommodate the release mechanism. In an embodiment, the tube portion **2** may be a

fixed length, such as, but is not limited to, about 2.5cm and the upper portion of the limbs **28** included in the short sheath **25** may be, but is not limited to, about 3cm. The tube portion **2** and the upper portion of the limbs **28** included in the short sheath **25** may be any suitable size depending upon the surgical procedure.

5 **[0084]** In another embodiment, shown in Figs. 14 and 15, once the surgical component package is opened by the inserter, the right limb **3** may be cut to the appropriate length, as determined by measurements made from a suitable imaging modality, including, but not limited to, a 3D CT scan. The left limb **4** may be trimmed also. In Figs. 14 and 16, longer sutures **14** are attached to the graft limbs **3** and **4**, and
10 the manufacturer supplied identification tags **21** may be applied or reapplied to the ends of the sutures.

[0085] In another embodiment shown in Fig. 17, an introducer sheath **95** with a detachable hemostatic valve **105** and a dilator **100** are illustrated as another embodiment of the present invention. The introducer sheath **95** and dilator **100** may be
15 passed over a support wire **11** from the right or left femoral artery up to the aortic neck. In Fig 18, the introducer sheath **95** may have a detachable or non-detachable hemostatic valve **105**, and the dilator **100** and wire **11** may be removed once the end of the introducer sheath **95** is placed at the level of the aortic neck. The introducer sheath **95** may have a soft or resilient portion **110** that can be clamped off.

20 **[0086]** As shown in Fig. 19, the short sheath **25** containing the graft may be introduced into the introducer sheath **95** and advanced until it meets a docking point **115**. The lumen of the short sheath **25** and that of the introducer sheath **95** may now be aligned so that easy transfer of the graft from the short sheath **25**. The introducer sheath **95** is stationary while the support wire **11** advances the graft within the lumen of
25 the introducer sheath. As the insertion apparatus is being introduced into the introducer sheath **95** the soft or resilient area **110** may be occluded to prevent blood loss while the hemostatic valve **105** is held open.

[0087] In Fig. 20, by pushing on the support wire **11**, the graft may be advanced to the area just before the soft area **110** of the introducer sheath **95**. At this point, the
30 graft may be entirely removed from the short sheath **25**. In Fig. 21, the short sheath **25** is removed. In Fig. 22, the occlusion mechanism at the soft or resilient area **110** is

removed. The graft may be advanced to the end of the introducer sheath **95** and poised for release. Fig. 23 depicts the attachment wires **12** in a spread-out manner when in fact the wires may be tightly compressed against the support wire and may only be released once the restraint of the introducer sheath is removed.

5 **[0088]** According to another embodiment of the present invention, Fig. 25 depicts a surgical component, which may be supplied to a physician in a short sheath **25** (now shown as opaque). A long delivery catheter **35**, as depicted in Fig. 24, may be brought into the sterile field. The long delivery catheter **35** is capable of receiving the contents of the short sheath **25** once the graft limbs are trimmed to the appropriate length and
10 long sutures, with attached tags are reattached to the graft limbs. The long delivery catheter **35** is also capable of insertion into the introducer sheath **95**. Thus, the long delivery catheter **35** must be of appropriate length and diameter to facilitate insertion within the introducer sheath to reach the vessel for repair.

[0089] According to Fig. 26, at the end **37** of the long delivery catheter **35** opposite
15 the portion that will be inserted into an artery there may be a connection mechanism so that a port or multiple ports with hemostatic seals can be attached. This will allow the support wire, the sutures attached to the graft limbs, and any other device to be inserted into the patient to either share a hemostatic port or to have separate ports for each or some combination of the above.

20 **[0090]** As shown in Fig. 26, the top **36** of the short sheath **25** is placed at the end **37** of the long delivery catheter **35** in preparation for the transfer of the graft assembly from the top **36** the short sheath **25** into the long delivery catheter **35**.

[0091] As depicted in Fig. 27, the short sheath **25** may be joined at its top to the long delivery catheter **35** at its bottom to form a junction **38**. The junction **38** may be a
25 locking joint that makes the inside appear seamless. The flare on the short sheath **26** assists in helping feed the graft into the short sheath **25** as the graft is pushed into the long delivery catheter **35** by pushing on the support wire **11**.

[0092] In Fig. 28, the entire graft has been advanced into the long delivery catheter **35** and the short sheath **25** has been removed. This graft transfer may be expedited by
30 having a lubricious inner surface on the sheaths.

[0093] In Fig. 29, the aneurysm diagram depicts a suprarenal aortic portion **39**, renal

arteries **40**, an infrarenal aortic neck **41**, an abdominal aortic aneurysm **42**, right **43** and left **44** common iliac arteries as well as their orifices **45** and **46**, and right **47** and left **48** external iliac and common femoral arteries. According to an embodiment of the present invention, the introducer sheath **95** may already have been inserted into the right femoral artery and advanced up to the level of the aortic neck **41**. The support wire **11** and the sutures **14** attached to the graft limbs both exit from the introducer sheath **95**. In an alternate embodiment of the present invention, the long delivery sheath **35** is inserted into an introducer sheath (not shown) in the right femoral artery **47** and advanced up to the level of the aortic neck **41**. The introducer sheath **95** inserted into the common femoral or external iliac artery **47** over a guide wire at the beginning of the procedure can be left in place for much, though not necessarily all of the procedure.

[0094] The end portion of the introducer sheath that is positioned within the aortic neck may be manufactured to be straight when the dilator **100** (Fig. 17) is in place. It may remain straight or it may assume a curved configuration once the dilator **100** is removed. The ability to tip deflect the end of the introducer sheath **95** by controls at the opposite end of the introducer sheath **95** outside the body may be adopted as part of the manufacturing process of the introducer sheath **95**. These controls may include manipulating wires through wires passing through longitudinal holes or by means of applying a current or some other force that would change the durometer of the end of the introducer sheath in a manner that would facilitate tip deflection. Such tip deflection would facilitate manipulating the tube portion of the graft **2** into an angulated aortic neck **41**.

[0095] In an embodiment shown in Fig. 30, a snare catheter **49** may be inserted through the opposite femoral artery, in this example, the left femoral artery **48** sheath (not shown) and the snare component **50** may be advanced over the attachment wires **12**. Use of a snare may reduce the introducer sheath's outside diameter. If space is available within the right larger introducer sheath, there may be a multiplicity of ways, for example, as referenced in the description of Fig. 7, to build in an expansion/retraction system to handle the expansion and retraction of the attachment wires **12**.

[0096] As shown in Fig. 31, the top of the introducer sheath **95** may be brought

above the orifices **40** of the renal arteries so that the ends of the graft limbs **3** and **4** are above the orifices **45** and **46** of the common iliac arteries.

[0097] In Fig. 32, the top **51** of the introducer sheath **95** may be pulled back while the support wire **11** is held steady so that the entire graft **1** is released from the introducer sheath. In this embodiment the snare component **50** prevents the top of the graft from expanding. As referenced in the description of Fig. 7, a catheter could also be passed over the support wire **11** and connected to a mechanism at the bulb **27** that would allow control of the angulation of the attachment wires **12** which would make the use of the snare optional.

[0098] According to Fig. 33, the top of the graft **5** may be placed within the aortic neck. As the graft is released, the right **3** and left **4** limbs of the bifurcation graft may not be under tension from the attached sutures **14** and may be contained within the aneurysm.

[0099] In Fig. 34, the snare component **50** is removed and, by holding the support wire **11** steady, the tube portion **2** of the graft remains in position within the aortic neck **41**. The attachment wires **12**, for the first time unrestrained, may hold the graft open. In an embodiment of the invention, the aorta is not occluded with the release of the graft. This approach may be less dangerous than techniques that require intermittent aortic occlusion because the heart is not subjected to large fluctuations in systemic vascular resistance. If the aorta is occluded near the level of the renal arteries, the pressure that the heart has to pump against is high. Indeed, systemic vascular resistance may be altered minimally with the approach presented in embodiments of the present invention.

[00100] As shown in Fig. 35, in this example, a snare catheter **49** is passed from the left femoral artery **48** out the right femoral artery **47**. The sutures **14** attached to the left limb **4** of the graft **1** may be placed within the snare component **50**. In Fig. 36, the identification tags **21** for the left medial and left lateral have been detached and are reattached once the sutures have been passed to the left side.

[00101] In Fig. 37, tension may be placed on the sutures **14** attached to the left limb **4** and also to the sutures **14** attached to the right limb **3** so that the limbs are brought down into the left **44** and right **43** common iliac arteries.

[00102] In an embodiment shown in Fig. 38, a fastener delivery catheter **53** may be inserted and positioned within the aortic neck **41** adjacent to or near the top of the tube portion **2** of the graft in order to initiate insertion of the fasteners **54**. The fastener delivery catheter **53** disclosed in U.S. Application No. 09/783,313 filed February 15, 2001, the disclosure and the subject matter is hereby incorporated herein by reference. The fastener catheter **53** may also provide any suitable type of fasteners, including, but not limited to, metal alloy, plastic, suture, wire, or any other suitable fastening mechanism.

[00103] In an embodiment shown in Fig. 39, fasteners **54** may be inserted circumferentially around the top **5** of the tube portion **2** of the graft **1**.

[00104] In an embodiment shown in Fig. 40, an electrical current may be applied to the support wire **11** by an actuator **55** outside the body of the patient. This causes the filaments attached to the attachment wires **12** to heat and sever the attached sutures **14**. Figs. 4, 5, and 6 detail an embodiment of the release mechanism using a current to increase temperature. Any suitable means may be used to effect release

[00105] Figs. 41 through 44 depict an embodiment of the release mechanism, and a method to remove the attachment wires **12** and the support wire **11** through the use of the snare component **50**. In Fig. 41, by advancing the wire **11**, the bulb **27**, and the attached attachment wires **12** may be advanced into the suprarenal aorta **39**. In Fig. 42, the snare catheter **49** is advanced through, by way of example, the right limb of the graft **3** and the snare component **50** is placed above the attachment wires **12**. As shown in Fig. 43, the snare component **50** may be tightened around the attachment wires **12** so that they may be brought close to the support wire **11**. In Fig. 44, the snare catheter **49** may be withdrawn through the right graft limb **3** bringing the attachment wires **12**. As referenced in the description of Fig. 7, there can be multiple other methods of facilitating the transition between an expanded and a contracted configuration of the attachment wires.

[00106] Figs. 45-47 illustrate securing the graft limbs to the left **44** and right **43** common iliac arteries. As shown in Fig. 45, the attachment wires have been removed and the right **3** and left **4** graft limbs are now ready for attachment within the right **43** and left **44** common iliac arteries. In Fig. 46, two stents **56** have been inserted into the

distal graft limbs **3** and **4** to provide an attachment means to the distal graft limbs.

[00107] In Fig. 47, the sutures **14** have been cut with a suture cutter **80**. The suture cutter **80** is shown in Figs. 66 and 67, and described in more detail below. The graft **1** is now securely attached to the aortic neck with fasteners **54** and to the common iliac arteries with stents **55**.

[00108] Instead of using the snare technique as shown in Figs. 30-33 and Figs. 42-44, an alternative embodiment uses a sheath as depicted in Figs. 48, 49, and 54. The attachment wires **12** are attached to the top **5** of the tube portion **2** of the graft **1**. The graft may be a supported graft or an unsupported graft. The insertion mechanism is composed of a central wire **57**. The central wire **57** may be bendable by the inserter to facilitate inserting the graft into an angled aortic neck. The central wire **57** attaches to a containment sheath **58** above the top **5** of the tube portion **2**. Instead of the attachment wires **12** being attached to the support wire **11**, they now are attached to a catheter **59** surrounding the central wire **57**. The central wire **57** and the support wire **11** function in a similar manner and may be made of the same material. Fig. 48 depicts the attachment wires **12** unsheathed.

[00109] The embodiment shown in Fig. 49 illustrates a way of supplying the graft positioned within a very short sheath **25** similar to the method described in Fig. 12. In this instance, however, the attachment wires **12** are enclosed and compressed toward the catheter **59** by the containment sheath **58**. Note that the manufacturer can supply the graft with just the tube portion in a short sheath **25**. The short sheath **25** may extend from the tube portion **2** to a portion over the limbs **28**, as depicted in Fig. 12 or may extend just over the tube **2**, as depicted in Fig 49.

[00110] Figs. 50, 51, and 52 provide additional embodiments of the present invention.

[00111] Fig. 50 provides a depiction of a very short sheath **25** connected to an open or partial sheath **63**. If desired, this can be connected to a solid component such as, but not limited to, wire or a synthetic, such as plastic or an open catheter **62**.

[00112] Fig. 51 depicts such a sheath in position within an aortic aneurysm. This example illustrates the tube portion **2** of the graft and attached to some wire **62** or partial catheter within it. Note that the manufacturer can supply the graft with just the tube portion in a very short sheath. This very short sheath **60** could allow the inserter to

shorten the graft limbs to the desired length as shown in Fig. 14 and then allow the graft **1** to be inserted directly into an introducer sheath **61**.

[00113] Fig. 52 is another embodiment of a sheath design analogous to that depicted in Fig. 50 though the catheter **62** would most likely have a lumen to allow a mechanism to pass through in order to deploy the graft **1**. This is a depiction of closed circumferential sheath **60** that becomes a partial or open sheath **63** that cones down **64** to an open catheter **62**.

[00114] Fig. 53 depicts a closed circumferential sheath **60** that becomes a partial or open sheath **63** that then resumes its closed circumferential sheath configuration **60** that then may end in a hemostatic valve **105**. Although not shown, the introducer sheath could be supplied with one or more soft or resilient areas, as depicted in Fig. 59, and the hemostatic valve could be replaced with a connector, as depicted in Fig. 60.

[00115] In Fig. 54, an electrical current is applied by an actuator **66** within the catheter **59** when it is desired to release the attachment wires **12** at the small attachment mechanism ball **15** attached to the sutures **14** that are in turn attached to the top **5** of the tube portion **2** of the graft. This release mechanism is also shown in Figs 4, 5 and 6. This current triggers the release mechanism. The containment sheath **58** in Fig 54 is depicted as no longer constraining the attachment wires **12**. This method of attachment and release can be used in holding and then detaching any foreign material such as, but not limited to, plastic, fabric, metal, alloy or any combination in any artery or vein or, indeed, in any tissue where a suture or other attachment device is intended to be a temporary (seconds, minutes, hours, days, months, years) attachment mechanism from which subsequent release may be desired. A similar release mechanism could be achieved with any object that changes character when exposed to energy such as light including, but not limited to, infrared and ultraviolet, sound waves, or electricity. Magnets and glues that dissolve upon electrical or heat stimulation or metal alloys that separate in response to heat or electrical current (this includes using resistive heating for activating a heat sensitive release mechanism for any foreign body within any vessel (artery or vein) or within any tissue space can also be used).

[00116] Fig. 55 depicts the attachment wires **12** captured within the containment sheath **58** and compressed toward the catheter **59**. The constraining and releasing of

the attachment wires illustrated is achieved by a push/pull mechanism. This could also be performed by a screwing mechanism, a ratcheting mechanism, or a twisting or turning mechanism.

[00117] Figs. 56 and 57 depict another embodiment to constrain (Fig. 56) and release (Fig. 57) the attachment wires **12** with pull wires **67**.

[00118] In an alternate embodiment, Fig. 58 depicts a method of attaching and detaching the attachment wires **12** to the tube portion **2** of the graft. The graft is constructed with a semi-rigid circumferential attachment hoop **72** in the neck of the graft **1**. The attachment hoop **72** may be composed of, but is not limited to, metal or polymer, or any other suitable material. The hoop serves as an attachment point **73** where the attachment wires **12** connect to splay or contract the graft **1**. The attachment wires **12** fasten to the attachment hoop **72** at intervals around the hoop either by the inserter or at the factory before sterilization. The attachment wires **12** may be, but are not limited to, circumferential struts. The struts can be normally splayed as shown, but is not limited to, a diameter of about 10-30mm or they can be normally axial with the support wire **11** and activated with secondary struts as is familiar in an umbrella opening mechanism. Schemes relating to reversible attaching and detaching are exemplary only and are not limited to those described below.

[00119] In one scheme, the attachment hoop is withdrawn from the strut, graft and the patient by an endovascular grasper allowing the struts to assume a position axial with the central catheter.

[00120] In a second scheme, the attachment hoop is a polymer that dissolves in blood in a time frame sufficient to carry out the correct placement and fastener attachment.

[00121] In a third scheme the attachment point detaches given sufficient force or energy which may include, but is not limited to electrical energy. With electrical energy the attachment point can soften and separate at the attachment points thus releasing the struts and the support wire. With electrical energy the strut end (attachment point) can assume a shape that releases the circumferential hoop.

[00122] It should be noted that the attachment hoop is not necessarily linear and can be shaped to be folded and inserted or can be shaped at the attachment points. Additionally, the attachment hoop does not necessarily need to be continuous and can

be intermittent and confined to the attachment points.

[00123] In a fourth scheme, the attachment hoop is a long flexible strand such as, but is not limited to metal or polymer of a length allowing it to extend to the exterior of the patient. In this scheme the strand is pulled and it releases the struts at the attachment points.

[00124] Fig 59 depicts the tube portion **2** of an graft contained within the short sheath **25** and the graft limbs **3** and **4** not constrained by the partial sheath portion **63** of the combination sheath. By way of example, Fig. 59 illustrates a graft within a sheath similar to that depicted in Fig. 50.

[00125] According to Fig. 60, the introducer sheath **95** may be, but is not limited to, about 3 to 30 French (F) (3 F = 1mm) in internal diameter. The introducer sheath **95** can have one or more soft or resilient areas **110** that may remain outside the artery or vein and can be clamped or snared to eliminate or reduce backflow of blood. The soft or resilient areas can be constructed of, but is not limited to, rubber, cloth, plastic or any other suitable material that is relatively compressible. A hemostatic valve **105** is also depicted. This valve can be replaced with a connector **78**, as illustrated in Fig. 61.

[00126] Fig. 61 depicts a variety of combinations of introducer sheaths **95** allowing the ability to construct, at the time of use, an introducer sheath that meets the needs of the individual inserting objects into a vessel, artery or vein. The basic sheath, Fig. 61A, may or may not have a soft area built in. It does have a connector **78** (snap-on, screw, latch etc.) that provides the ability to connect a variety of extensions or additional ports. Fig. 61B depicts an extender that has two soft areas **110** and a hemostatic valve **105**. Fig. 61C has only one soft area **110** and a valve **105** whereas Fig. 61D has a soft area and a connector **78** on each end. Fig. 61E offers the possibility of adding multiple ports.

These embodiments are some of the possible variations of connectors, soft areas and hemostatic valves that could be constructed and are intended to be illustrative and exemplary only.

[00127] Fig. 62 shows that, within the inner wall **79** of the introducer sheath **95**, there can be constructed a small port **81**, **82** or multiple ports for the infusion of a liquid such as, but not limited to, a heparin solution. The ports **81**, **82** link to a passageway **92** or a plurality of passageways that may extend the length of the introducer sheath or a

predetermined length. The entrance of the port **82** may be near the connector **78** or hemostatic valve **105** outside the area of insertion into the artery or vein. The ports exit site(s) may be near the top of the introducer sheath into the lumen **83** or multiple exit points at discreet places along the length or continuously along the length from proximal to distal. The method of distributing the infusate distally can be via a lumen in the internal diameter, in the wall or on the outside of the sheath wall via a secondary lumen.

[00128] The introducer sheath may have a simple sheath with a side infusion port and hemostatic valve or a simple sheath with a side infusion port and snap-on connector or sheath with soft area with infusion port or any combination thereof. Fig. 63 is a cross-section of the introducer sheath showing the infusion port **81**.

[00129] Fig. 64 depicts an introducer sheath **95** containing one soft spot **110** with a connector **78** attached to a double port **84**. Each has a soft spot **110** and a hemostatic valve **105**. Fig. 64 demonstrates how the connectors work and also shows that the lumens of the add-on ports and extenders can be of varying diameters.

[00130] Fig. 65 depicts another possible feature of the introducer sheath **95** with a soft or resilient section **110**, also illustrated in Fig. 61. This is a user-controlled variable restricting device **85** that is in circumferential contact with the resilient section **110**. The user-controlled variable restricting device **85** is adjustable for the desired internal aperture of the resilient section. The desired internal aperture can be fully open for the largest outer diameter catheter **A**, partially open for hemostasis around any size catheter (including a guide wire) **B**, or fully closed for total hemostasis **C**. The purpose of the device is aperture control and thereby accommodating most sizes of devices passing through the internal diameter of the introducer sheath.

[00131] An advantage of alternative embodiments of the invention depicted in Figs. 66 and 67 is to cut a suture along its length at a location remote from the operator and for the device to track over a suture or along side of it by a suture cutter **80**. Fig. 66 shows a catheter based device **80** which tracks over a suture **14** to a remote location and cuts the suture at the distal end of the catheter when the operator inputs mechanical energy into the mechanical actuator **86**. In this example the mechanical actuator **86** is pushed and the cutter **87** moves through the suture **14** and cuts it in two pieces **88** and **89**. When the mechanical actuator **86** is withdrawn the counter-

resistance mechanism **90** such as, but not limited to, spring, flex band as shown, or any other suitable counter-resistance mechanism causes the cutter **87** to return to its original position. Alternatively a spring can act as the force driving the cutter through the suture when the mechanical actuator is withdrawn. Also, the actuator and cutter can be arranged so that rotational or linear movement will cause the cutter to pass through the suture and cut it. An alternative method of affecting the cut of the suture can be laser light. The source of laser light immediately adjacent to the suture would be an optical fiber or a laser diode.

[00132] It is further noted that the suture can be fed through the lumen of the suture cutter via a simple snare. If the suture cutter tracks along side of the suture, the suture can be fed through a shorter lumen either axially or from the side. A side loading design would allow the suture to enter from the side but not allow its exit during the tracking procedure prior to cutting.

[00133] It will be apparent to those skilled in the art that variations and modifications of the present invention can be made without departing from the scope or spirit of the invention. For example, the method of performing a surgical procedure could be used in settings other than the repair of aneurysms. The method could be used to attach any prosthetic material to any tissue with a metal or plastic attachment device, such as a shape memory metal, plastic staple, or metal staple. For instance, the method could be used to attach a prosthetic mesh to fascia through a laparoscope/endoscope or directly in an open operation for hernia repair. Thus, it is intended that the present invention cover all such modifications and variations of the invention, provided they come within the scope of the appended claims and their equivalents.

WHAT IS CLAIMED IS:

1. An insertion apparatus for deploying a surgical component to a site in a vessel comprising:
 - 5 attachment means for attaching the surgical component to the insertion apparatus, wherein the attachment means is releasably connected to the surgical component; and

release means for releasing the attachment means from the surgical component, wherein the release means is in communication with the attachment means.
- 10 2. The insertion apparatus of Claim 1, further comprising fastening means for fastening the surgical component to the vessel.
3. The insertion apparatus of Claim 1, wherein the surgical component is a graft.
4. The insertion apparatus of Claim 1, wherein the release means supplies an electric current to the attachment means.
- 15 5. The insertion apparatus of Claim 1, wherein the release means supplies heat to the attachment means.
6. The insertion apparatus of Claim 1, wherein the surgical component comprises at least one distinctive marker.
7. The insertion apparatus of Claim 1, wherein the attachment means comprises at
20 least one attachment wire and a support wire.
8. The insertion apparatus of Claim 1, wherein the attachment means comprises an attachment hoop, at least one attachment wire, and a support wire.
9. The insertion apparatus of Claim 1, wherein the insertion apparatus further comprises a short sheath.
- 25 10. The insertion apparatus of Claim 9, wherein the short sheath comprises a flare.

11. The insertion apparatus of Claim 1, wherein the surgical component corresponds to the site in the vessel with an appropriate diameter and length.

12. An insertion apparatus for deploying a surgical component to a site in a vessel comprising:

- 5 at least one attachment wire with a first end and a second end;
 a support wire ;

 wherein the first end of the at least one attachment wire is releaseably connected to the surgical component and the second end is connected to the support wire; and

 wherein the attachment wire and support wire positions the surgical component
10 at a site in the vessel.

13. The insertion apparatus of Claim 12, further comprising a fastener delivery catheter.

14. The insertion apparatus of Claim 12, wherein the surgical component is a graft.

15 15. The insertion apparatus of Claim 12, further comprising an electric current
supplied to the attachment wire for releasing the surgical component.

16. The insertion apparatus of Claim 12, wherein the surgical component comprises at least one distinctive marker.

17. The insertion apparatus of Claim 12, wherein the insertion apparatus further comprises a short sheath.

20 18. The insertion apparatus of Claim 17, wherein the short sheath comprises a flare.

19. The insertion apparatus of Claim 12, wherein the surgical component corresponds to the site in the vessel with an appropriate diameter and length.

20. The insertion apparatus of Claim 12, further comprising an introducer sheath.

21. The insertion apparatus of Claim 20, wherein the introducer sheath comprises a

homostatic valve and a dilator.

22. The insertion apparatus of Claim 20, wherein the introducer sheath comprises at least one soft portion.

23. The insertion apparatus of Claim 22, wherein the soft portion is a user-controlled variable restricting device wherein the soft portion is adjustable.

24. The insertion apparatus of Claim 20, wherein the introducer sheath is a closed circumferential sheath.

25. The insertion apparatus of Claim 20, wherein the introducer sheath is an open sheath.

10 26. An insertion apparatus for deploying a surgical component to a site in a vessel comprising:

an attachment hoop releasably connected to the surgical component;

at least one attachment wire with a first end and a second end;

a support wire;

15 wherein the first end of the at least one attachment wire is connected to the attachment hoop and the second end of the at least one attachment wire is connected to the support wire; and

wherein the insertion apparatus positions the surgical component in the vessel.

20 27. The insertion apparatus of Claim 26, further comprising a fastener delivery catheter.

28. The insertion apparatus of Claim 26, wherein the surgical component is a graft.

29. The insertion apparatus of Claim 26, further comprising an electric current supplied to the attachment hoop for releasing the surgical component.

30. The insertion apparatus of Claim 26, wherein the surgical component comprises

at least one distinctive marker.

31. The insertion apparatus of Claim 26, wherein the surgical component further comprises a short sheath.

32. The insertion apparatus of Claim 31, wherein the short sheath comprises a flare.

5 33. The insertion apparatus of Claim 26, wherein the surgical component corresponds to the site in the vessel with an appropriate diameter and length.

34. The insertion apparatus of Claim 26, further comprising an introducer sheath.

35. The insertion apparatus of Claim 34, wherein the introducer sheath comprises a detachable homostatic valve and a dilator.

10 36. The insertion apparatus of Claim 34, wherein the introducer sheath comprises at least one soft portion.

37. The insertion apparatus of Claim 36, wherein the soft portion is a user-controlled variable restricting device wherein the soft portion is adjustable.

15 38. The insertion apparatus of Claim 34, wherein the introducer sheath is a closed circumferential sheath.

39. The insertion apparatus of Claim 34, wherein the introducer sheath is an open sheath.

40. An insertion system for deploying a surgical component to a site in a vessel comprising:

20 a surgical component;

an insertion apparatus;

attachment means for attaching the surgical component to the insertion apparatus, wherein the attachment means is releasably connected to the surgical component; and

release means for releasing the attachment means from the surgical component, wherein the release means is in communication with the attachment means.

41. The insertion system of Claim 40, further comprising a fastening means for fastening the surgical component to the vessel.

5 42. The insertion system of Claim 40, further comprising an introducer sheath.

43. The insertion system of Claim 42, wherein the introducer sheath comprises a homostatic valve and a dilator.

44. The insertion system of Claim 42, wherein the introducer sheath comprises at least one soft portion.

10 45. The insertion system of Claim 44, wherein the soft portion is a user-controlled variable restricting device wherein the soft portion is adjustable.

46. The insertion system of Claim 42, wherein the introducer sheath is a closed circumferential sheath.

15 47. The insertion system of Claim 42, wherein the introducer sheath is an open sheath.

48. The insertion system of Claim 40, further comprising a fastener delivery catheter.

49. The insertion system of Claim 40, wherein the surgical component is a graft.

50. The insertion system of Claim 40, wherein the surgical component comprises at least one distinctive marker.

20 51. The insertion system of Claim 40, wherein the insertion apparatus further comprises a short sheath.

52. The insertion system of Claim 51, wherein the short sheath comprises a flare.

53. The insertion system of Claim 40, wherein the surgical component corresponds to the site in the vessel with an appropriate diameter and length.

54. The insertion system of Claim 40, wherein the surgical component comprises at least one distinctive marker.
55. The insertion system of Claim 40, wherein attachment means comprises at least one attachment wire and a support wire.
- 5 56. The insertion system of Claim 40, wherein attachment means comprises an attachment hoop, at least one attachment wire, and a support wire.
57. The insertion system of Claim 40, wherein release means comprises an electric current supplied to attachment means for release of the attachment means from the surgical component.
- 10 58. A method for positioning a surgical component to a site in a vessel comprising the steps of:
- introducing an insertion apparatus proximal to the site in the vessel;
 - activating the insertion apparatus; and
 - withdrawing the insertion apparatus.
- 15 59. The method of Claim 58, further comprising the step of inserting an introducer catheter to the site in the vessel prior to introducing the insertion apparatus to the site in the vessel.
60. A method for positioning a surgical component with an insertion apparatus to a site in a vessel comprising the steps of:
- 20
- introducing the insertion apparatus proximal to the site in the vessel;
 - fastening the surgical component to the vessel;
 - activating the insertion apparatus; and
 - withdrawing the insertion apparatus.

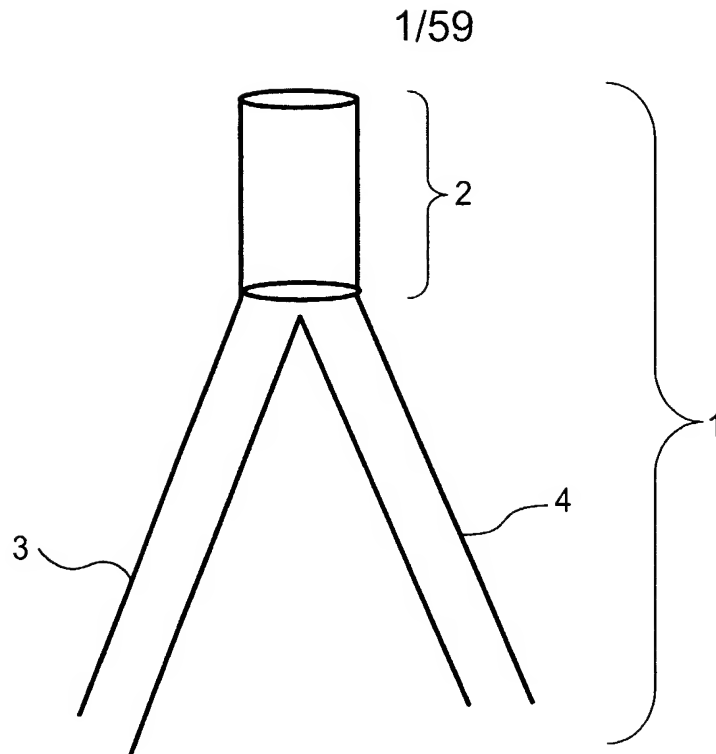


FIG. 1

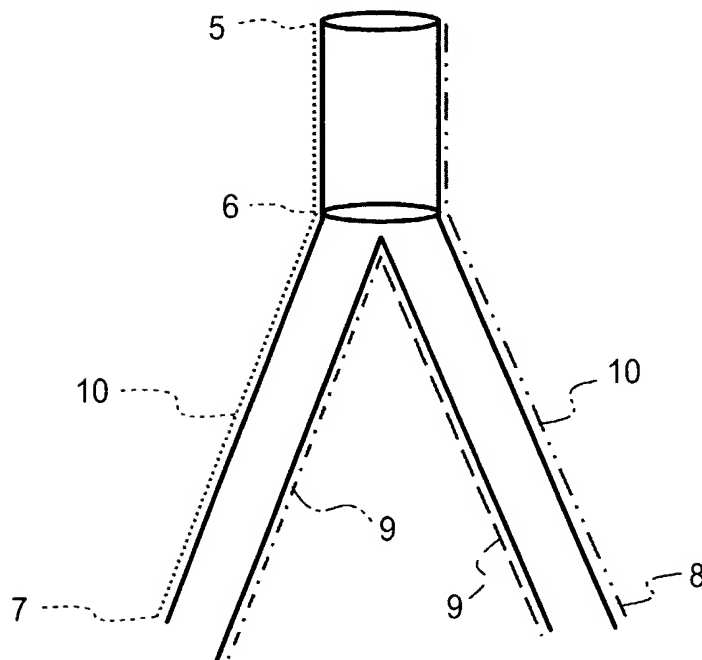
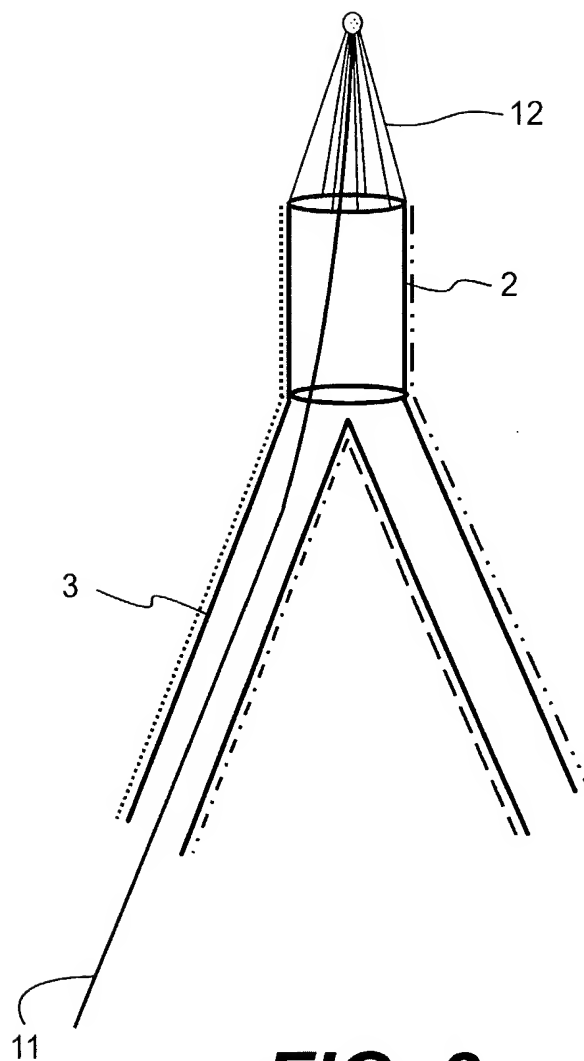


FIG. 2

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**FIG. 3**

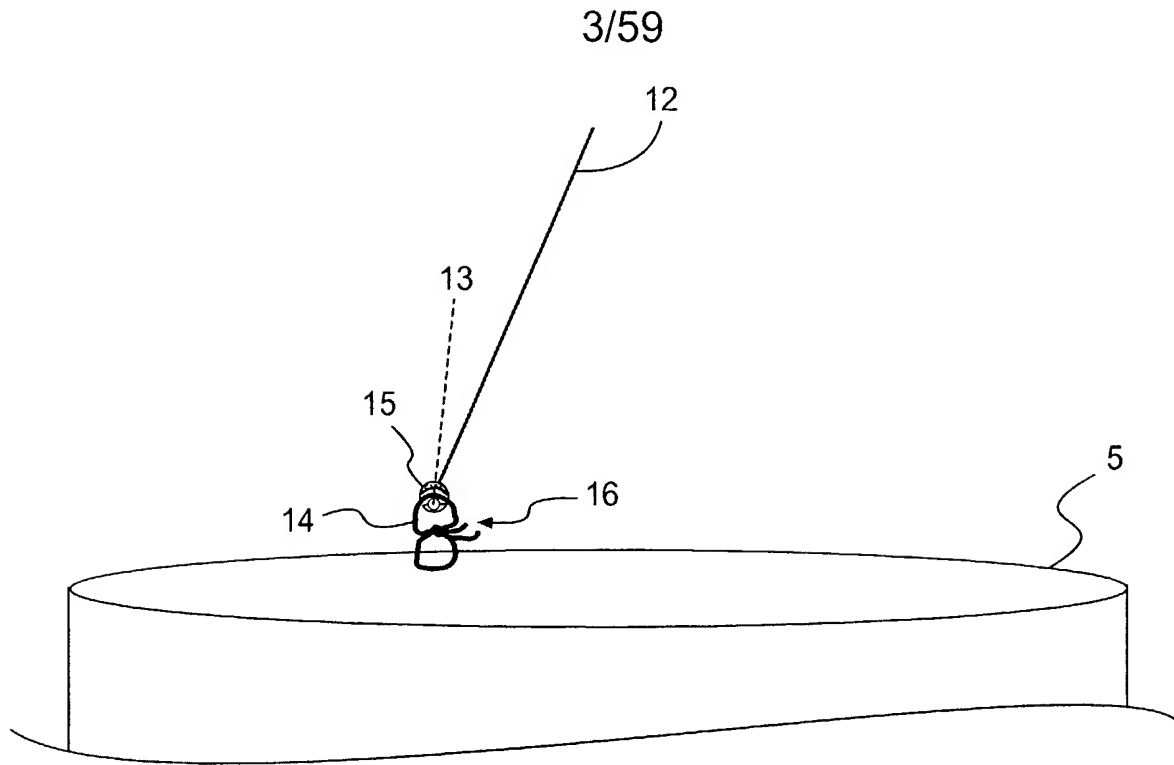
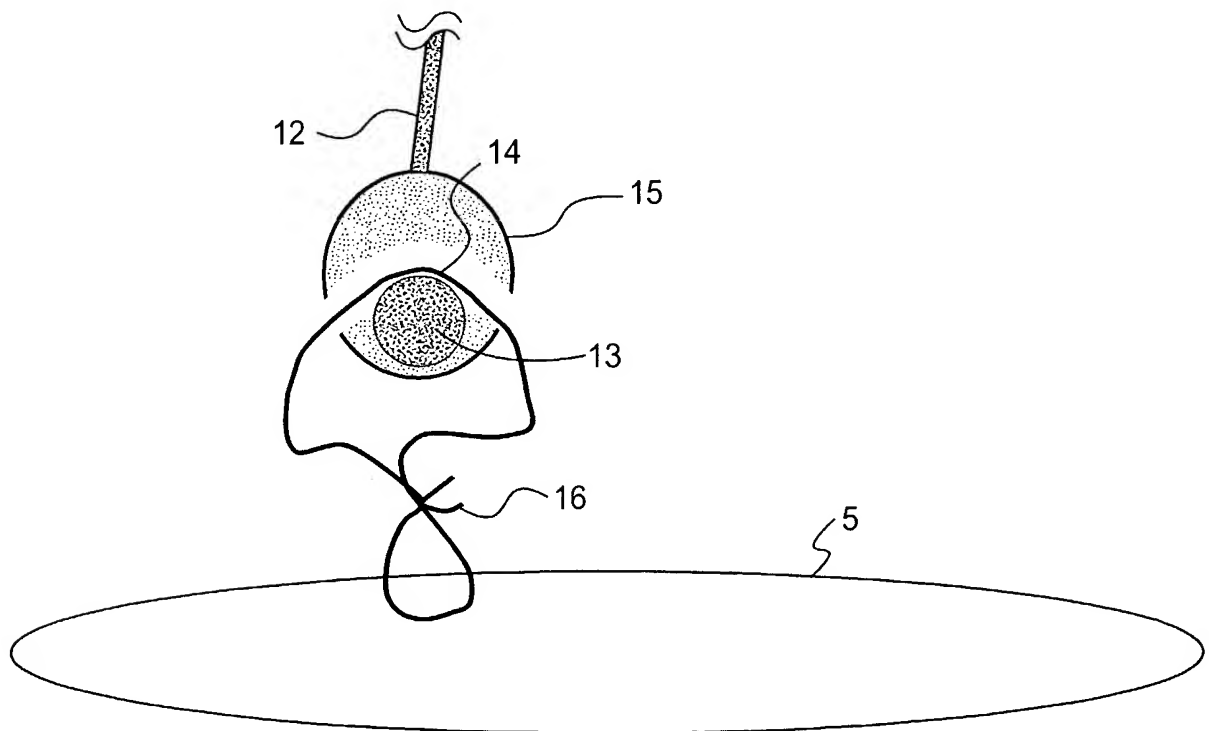
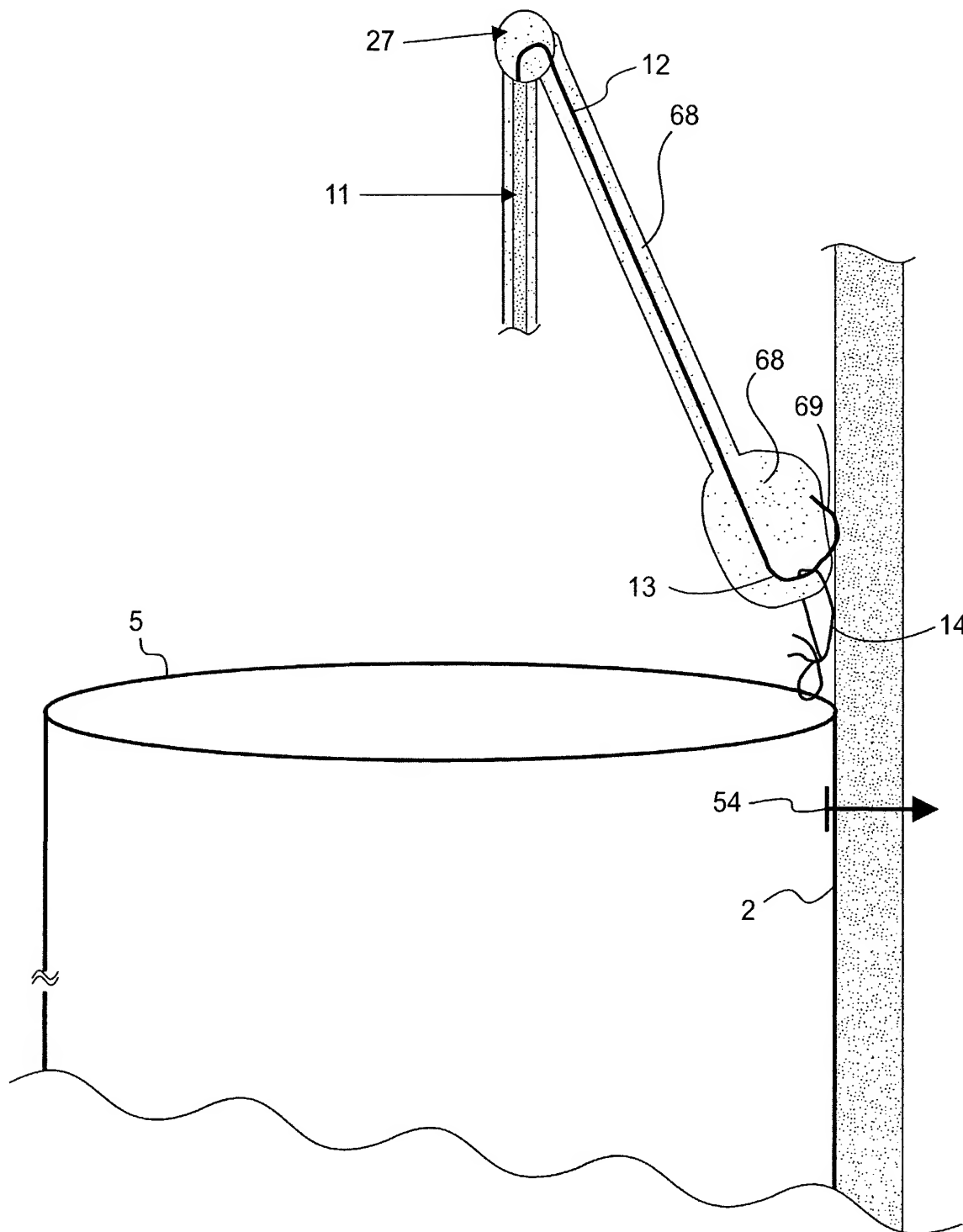


FIG. 4



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**FIG. 6**

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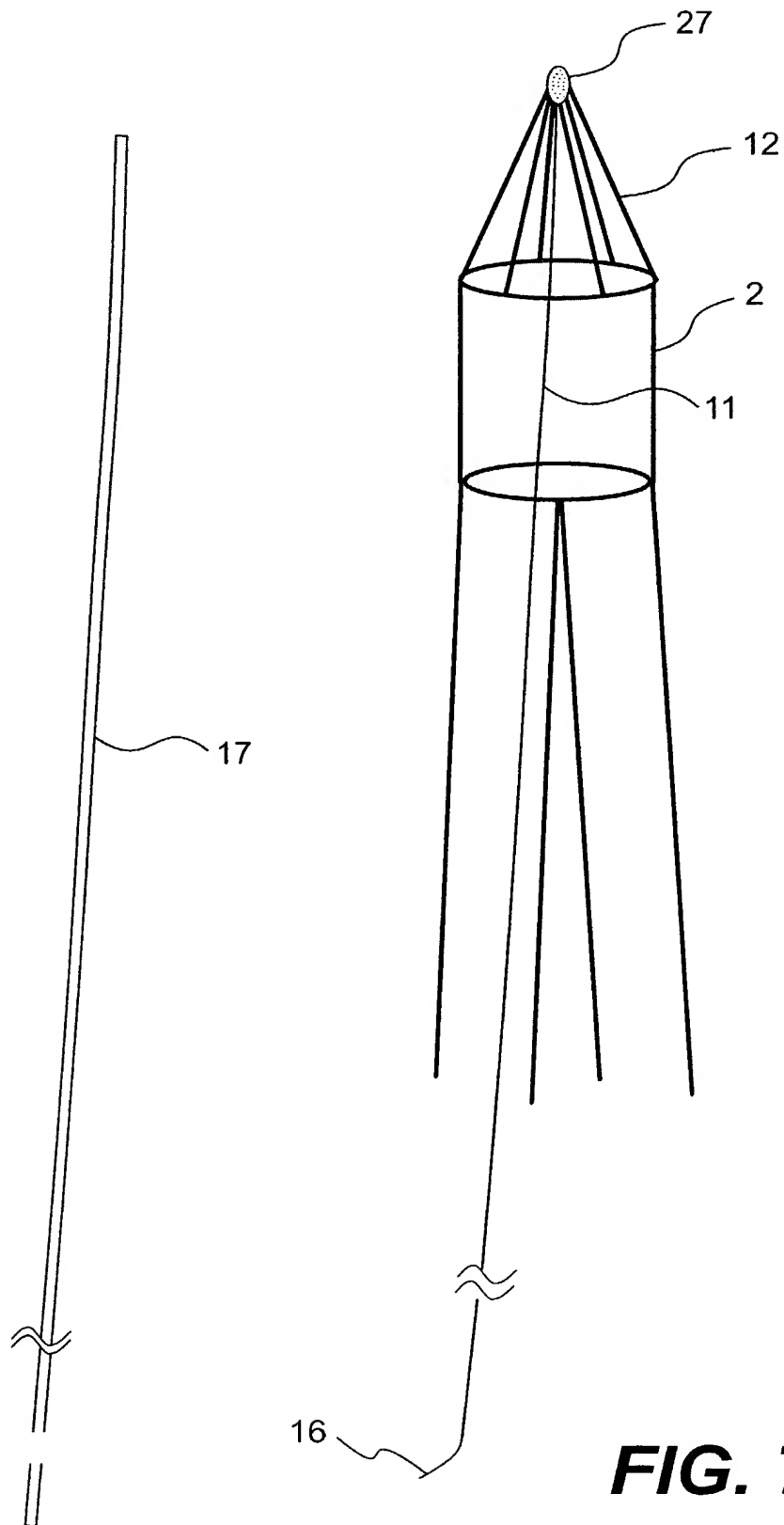


FIG. 7

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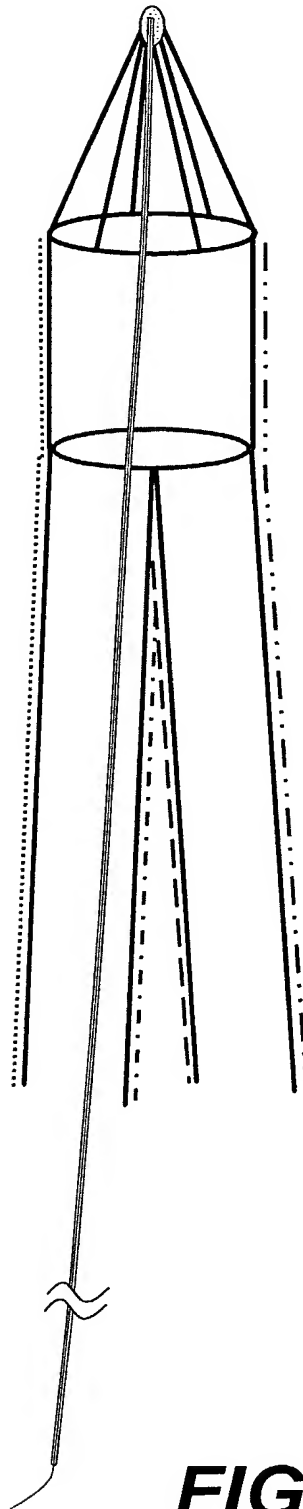


FIG. 8

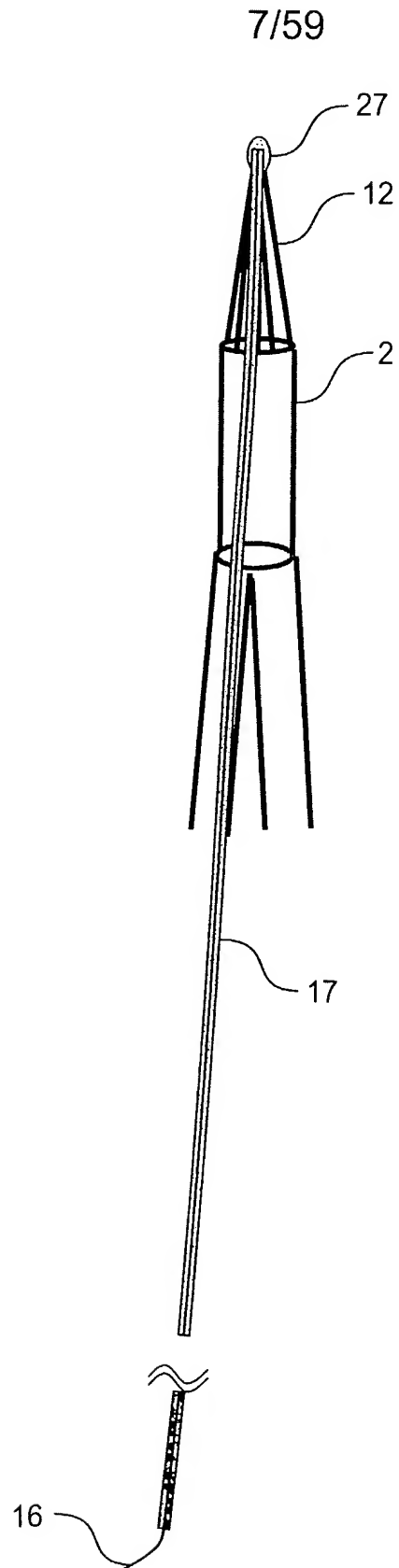


FIG. 9

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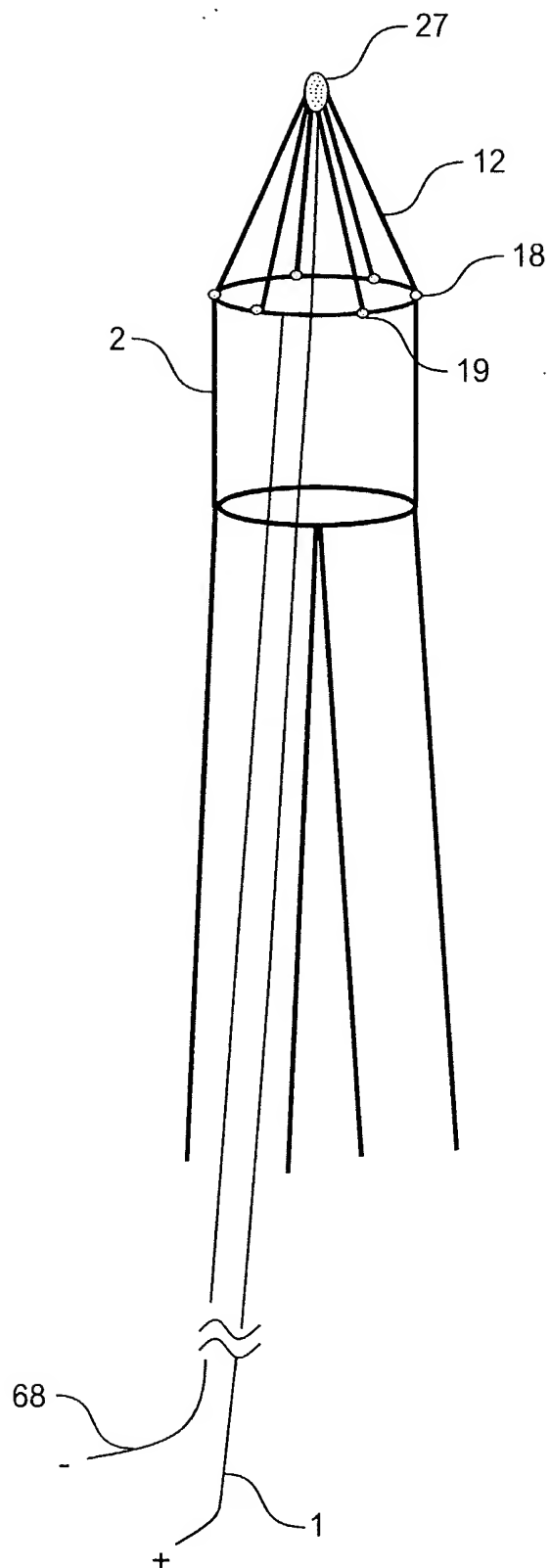
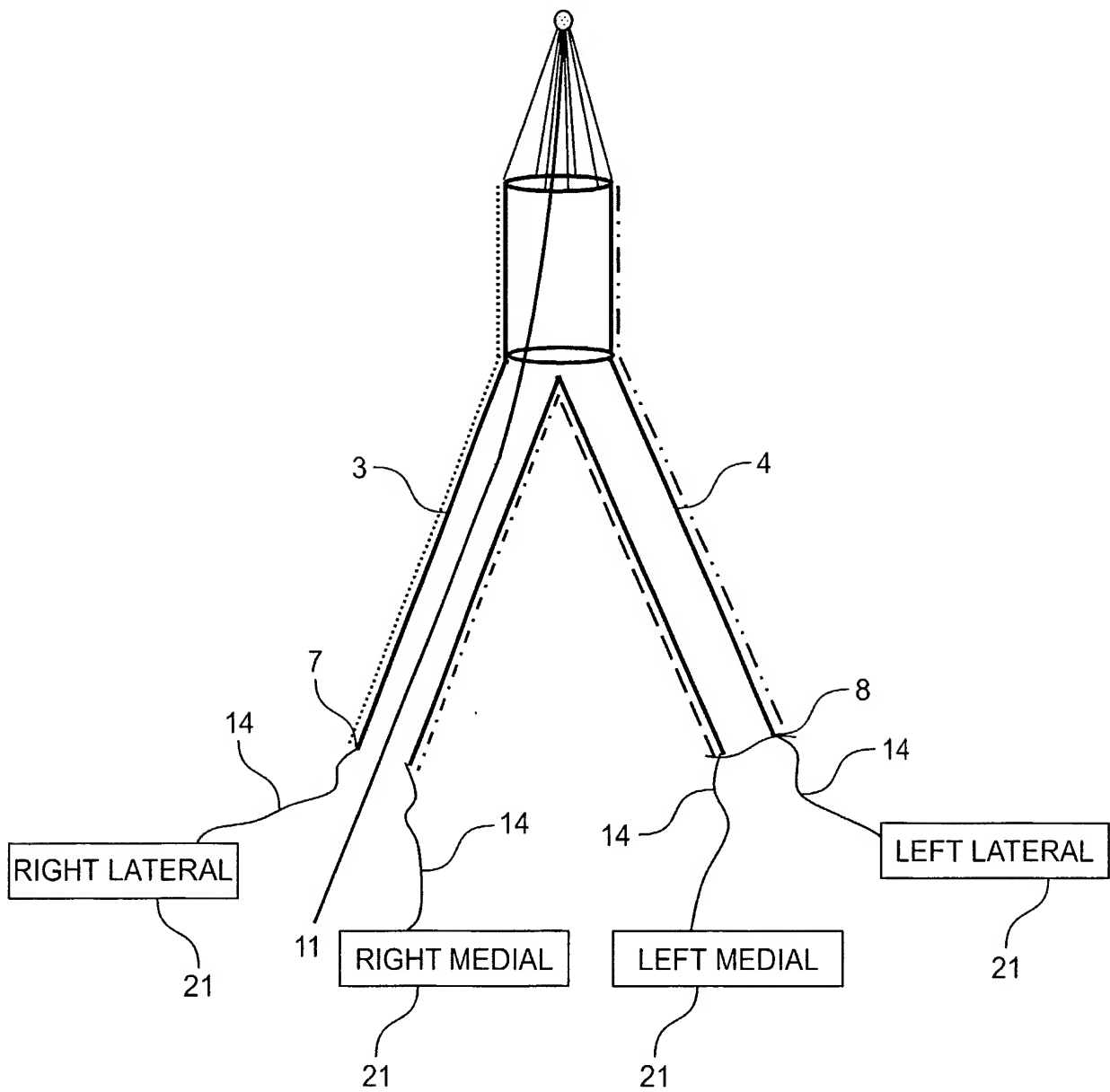
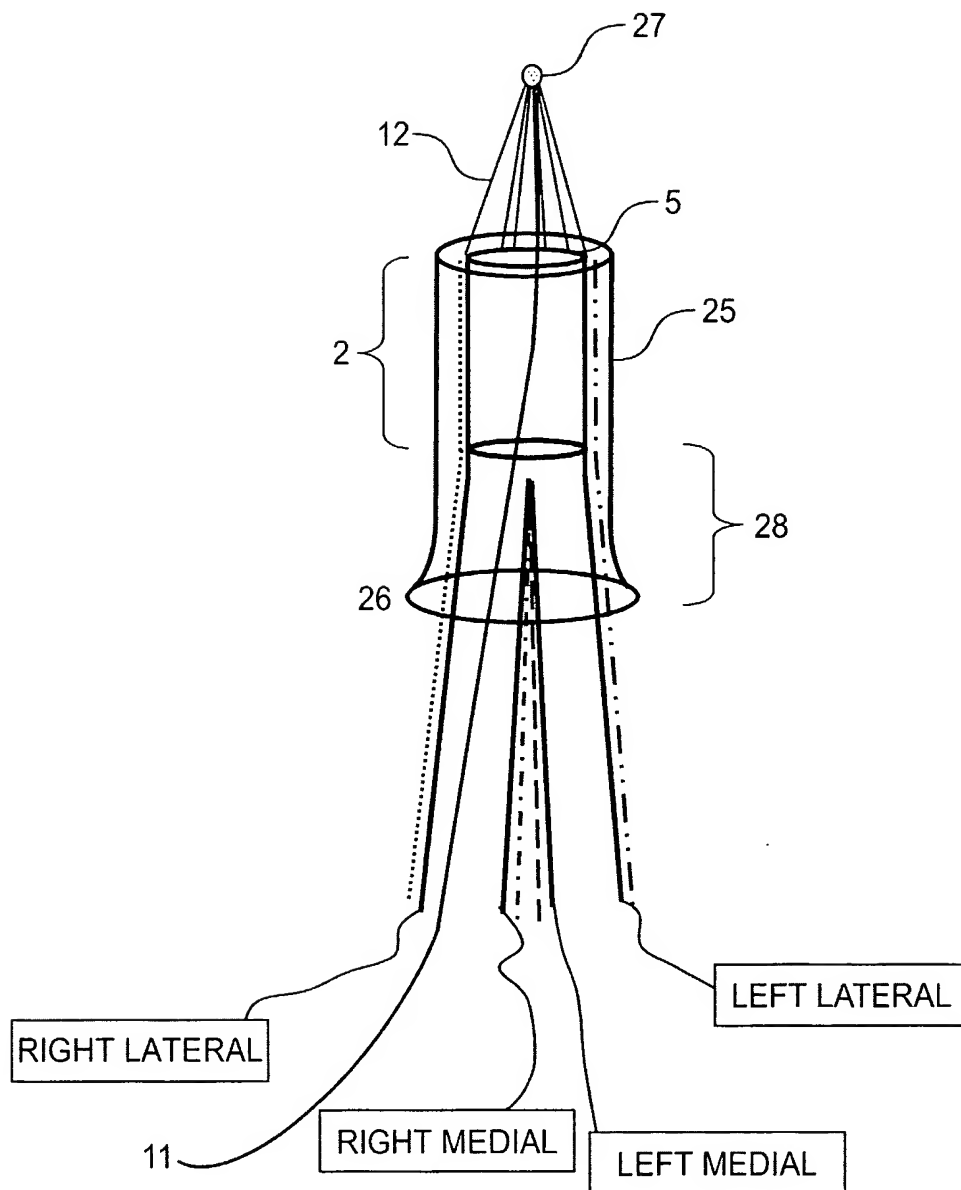


FIG. 10

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**FIG. 11**

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**FIG. 12**

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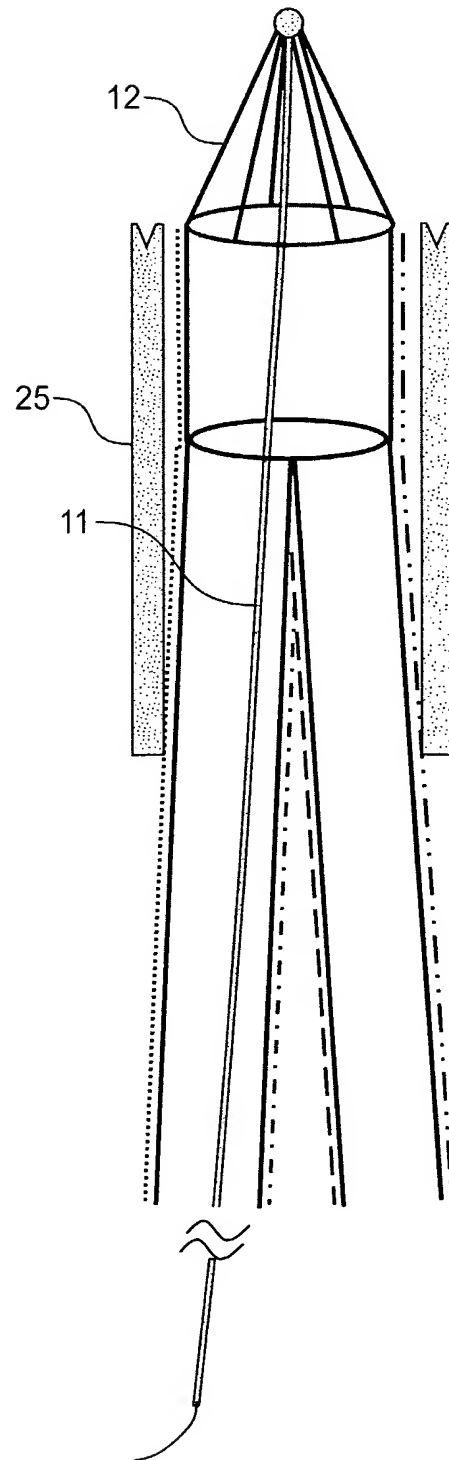


FIG. 13

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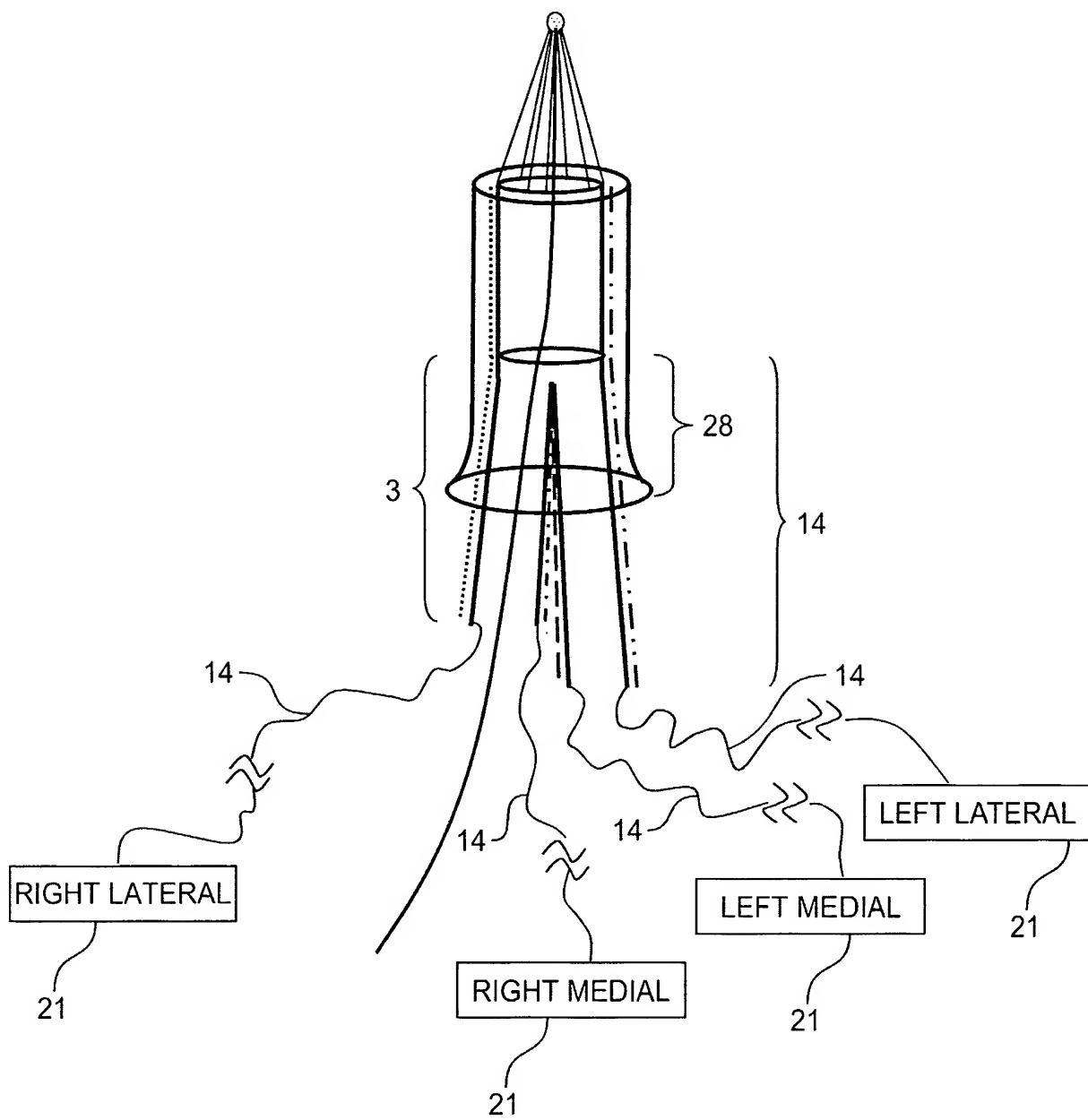


FIG. 14

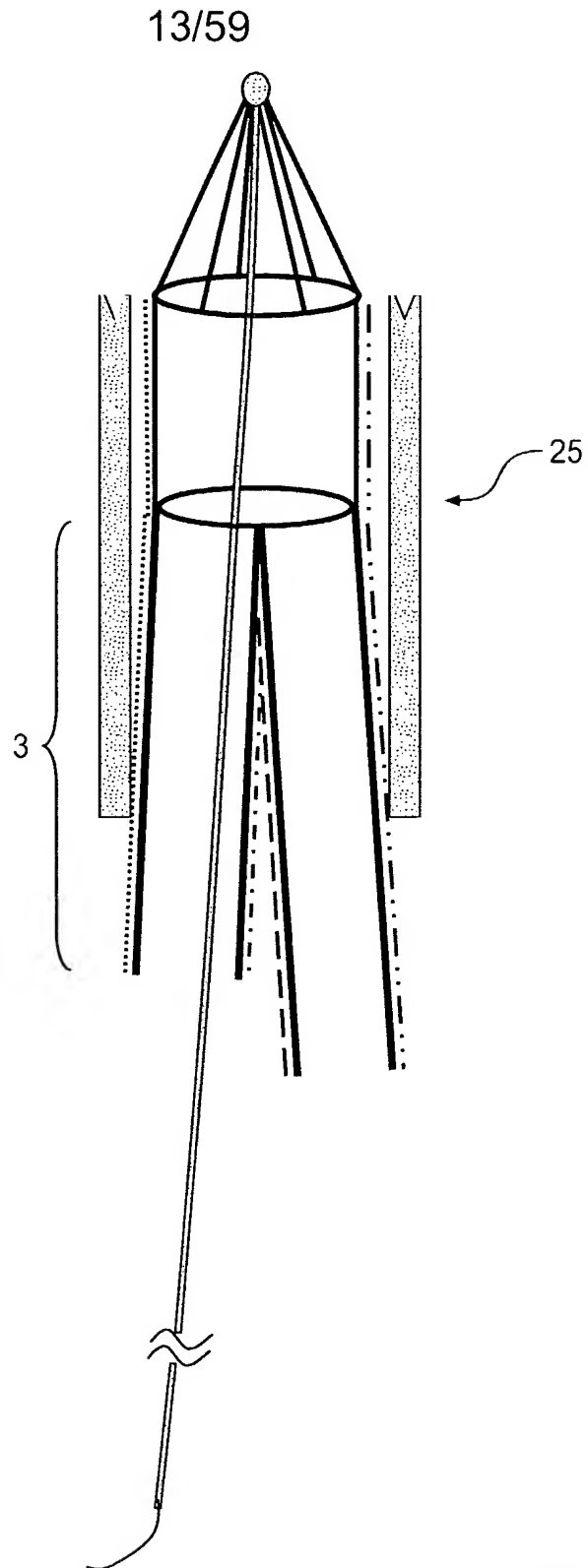
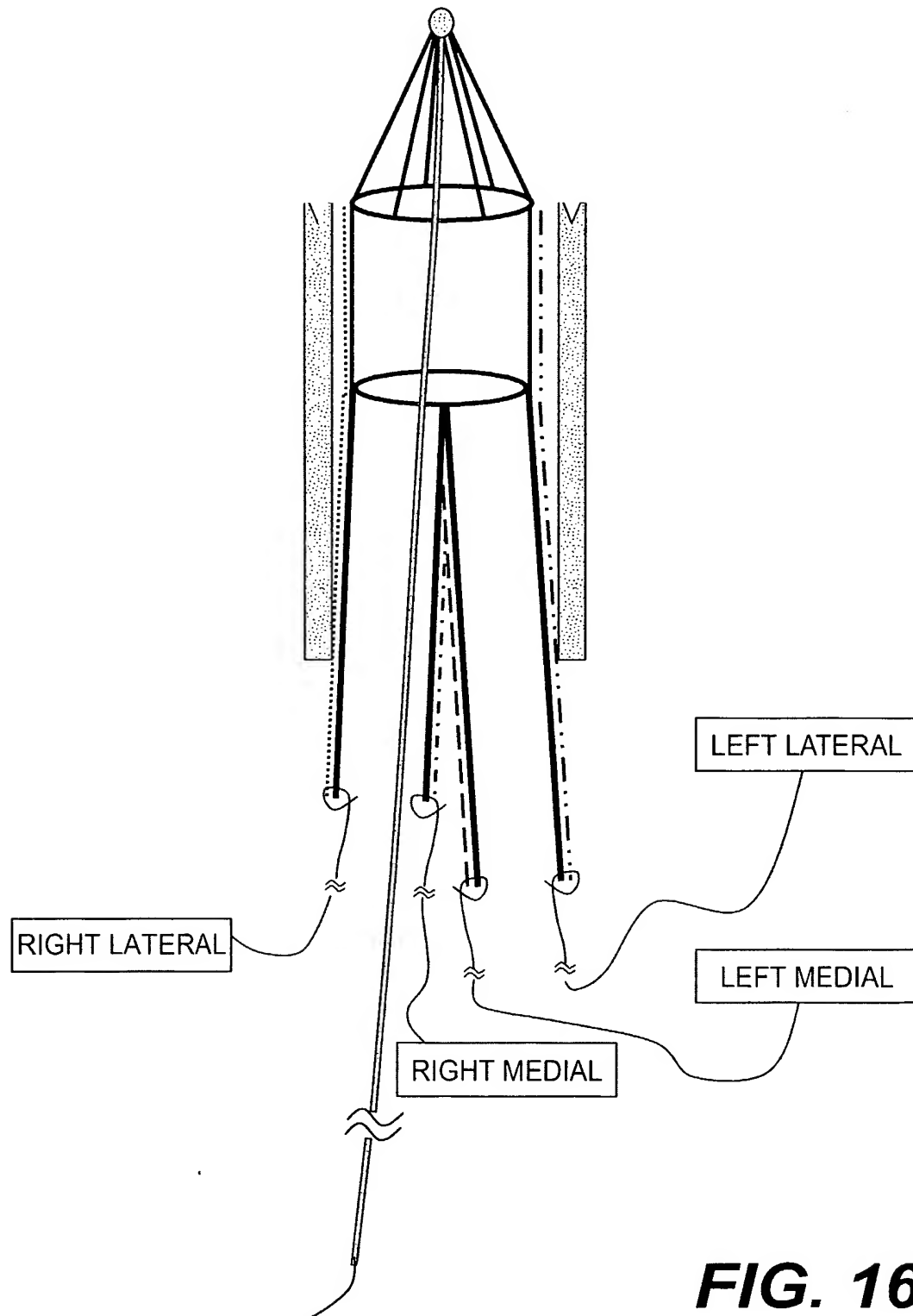


FIG. 15

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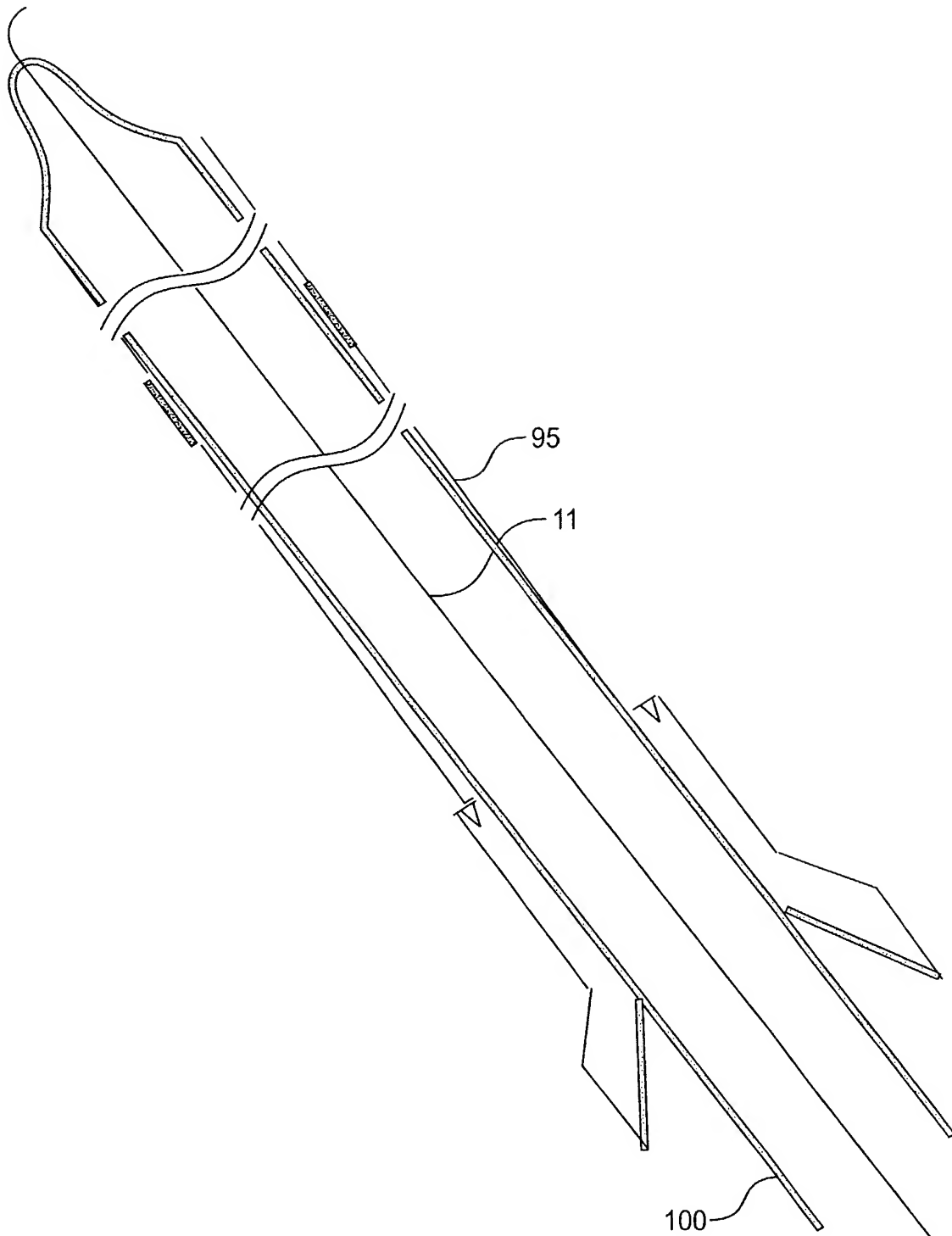


FIG. 17

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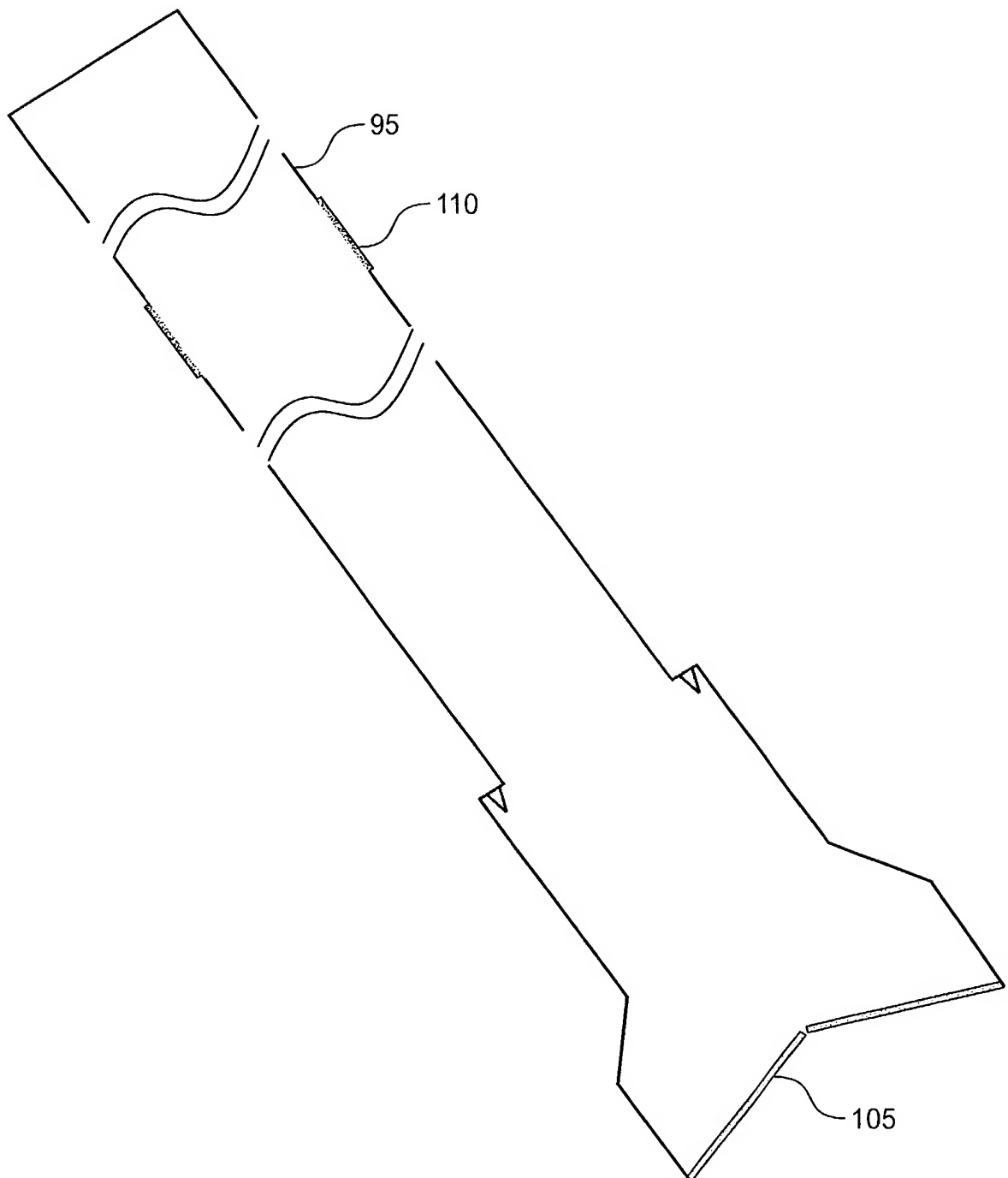


FIG. 18

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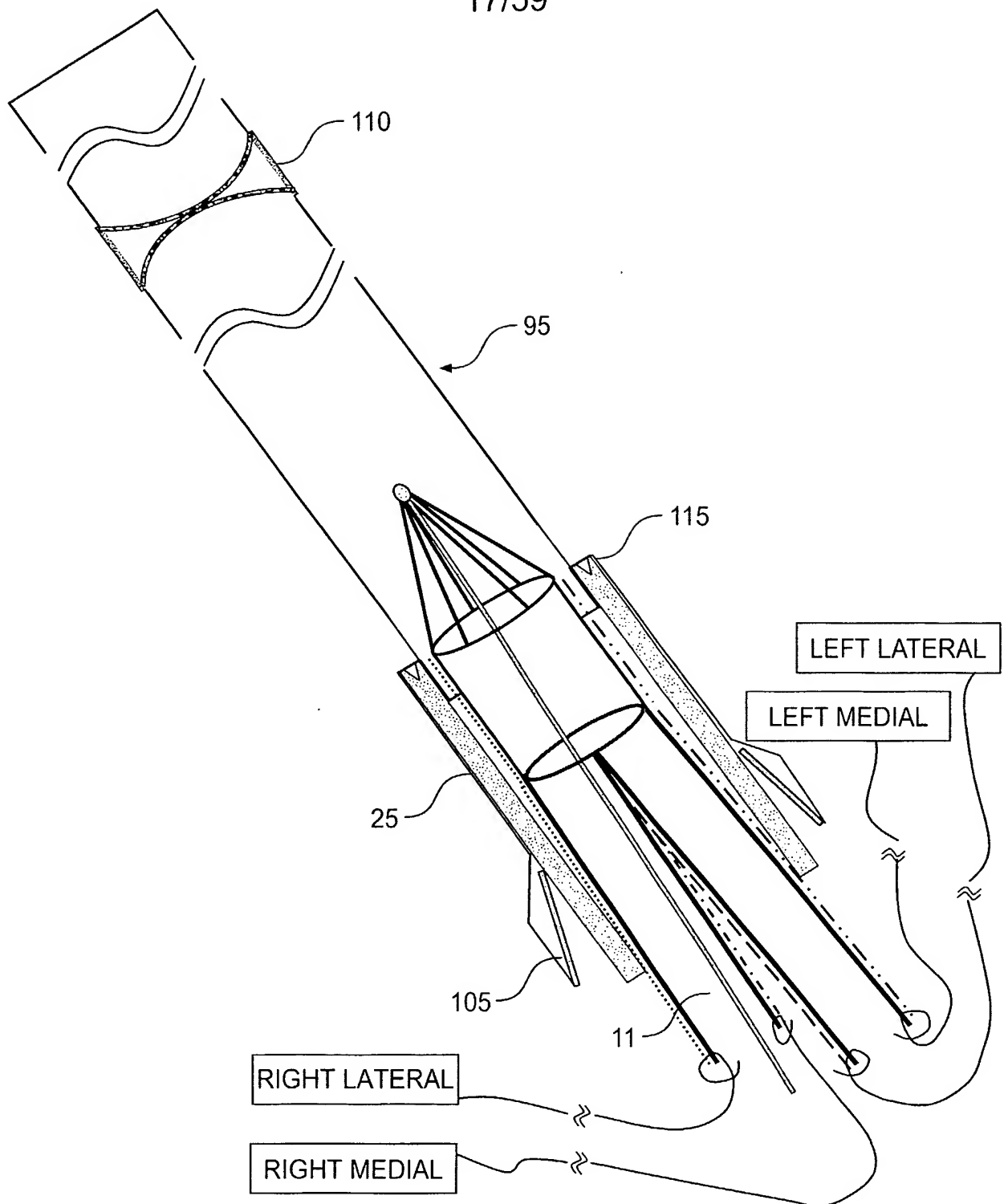


FIG. 19

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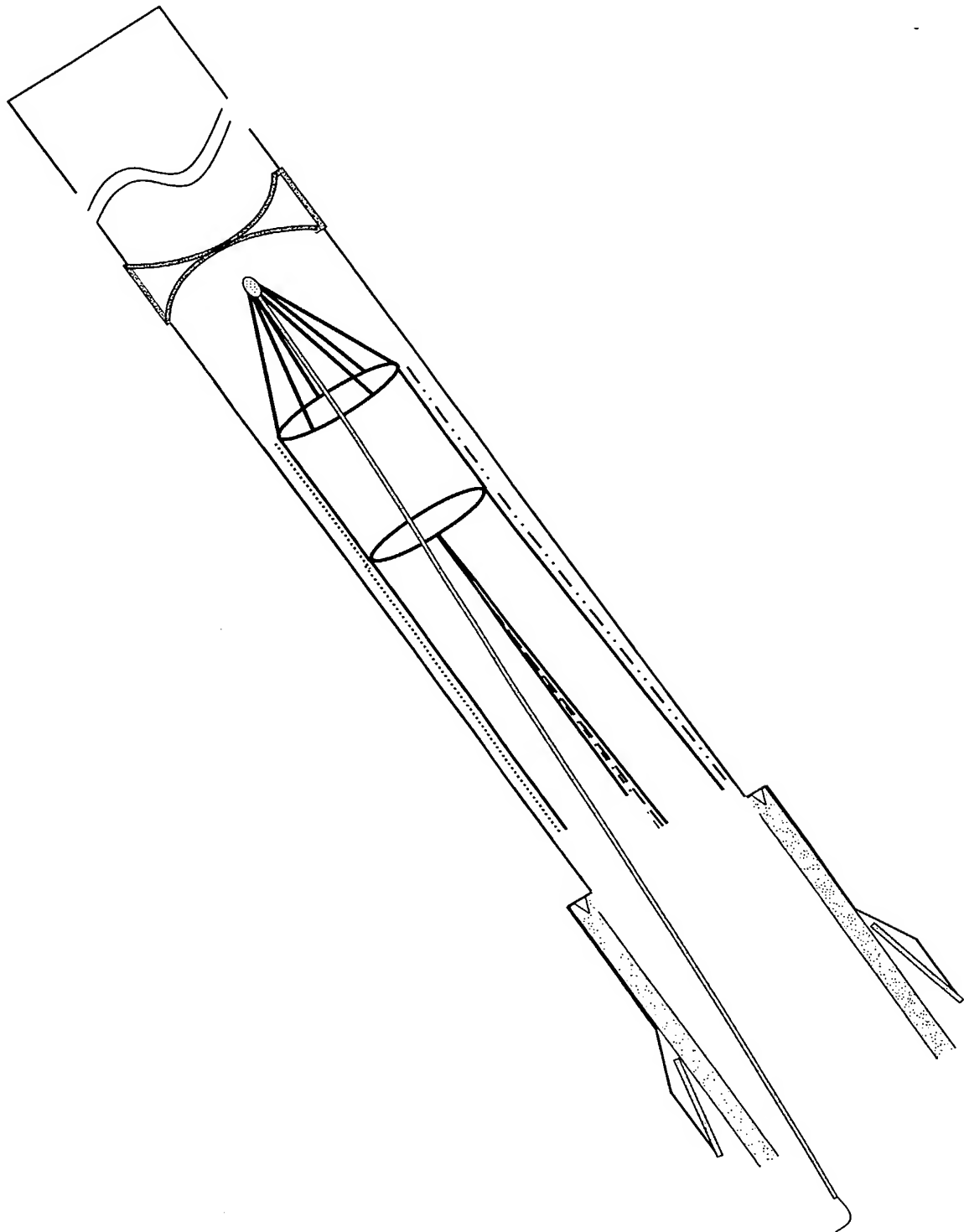


FIG. 20

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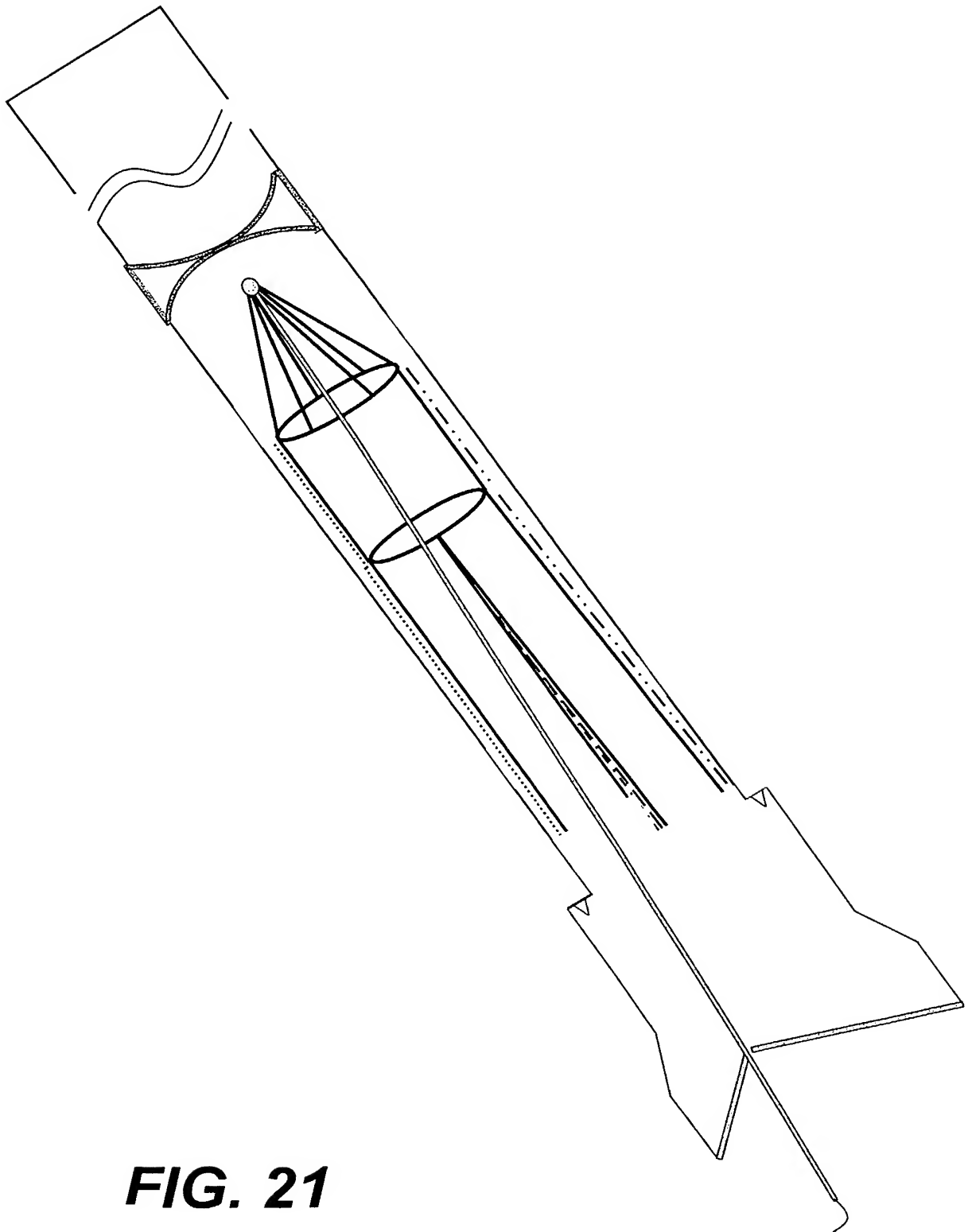
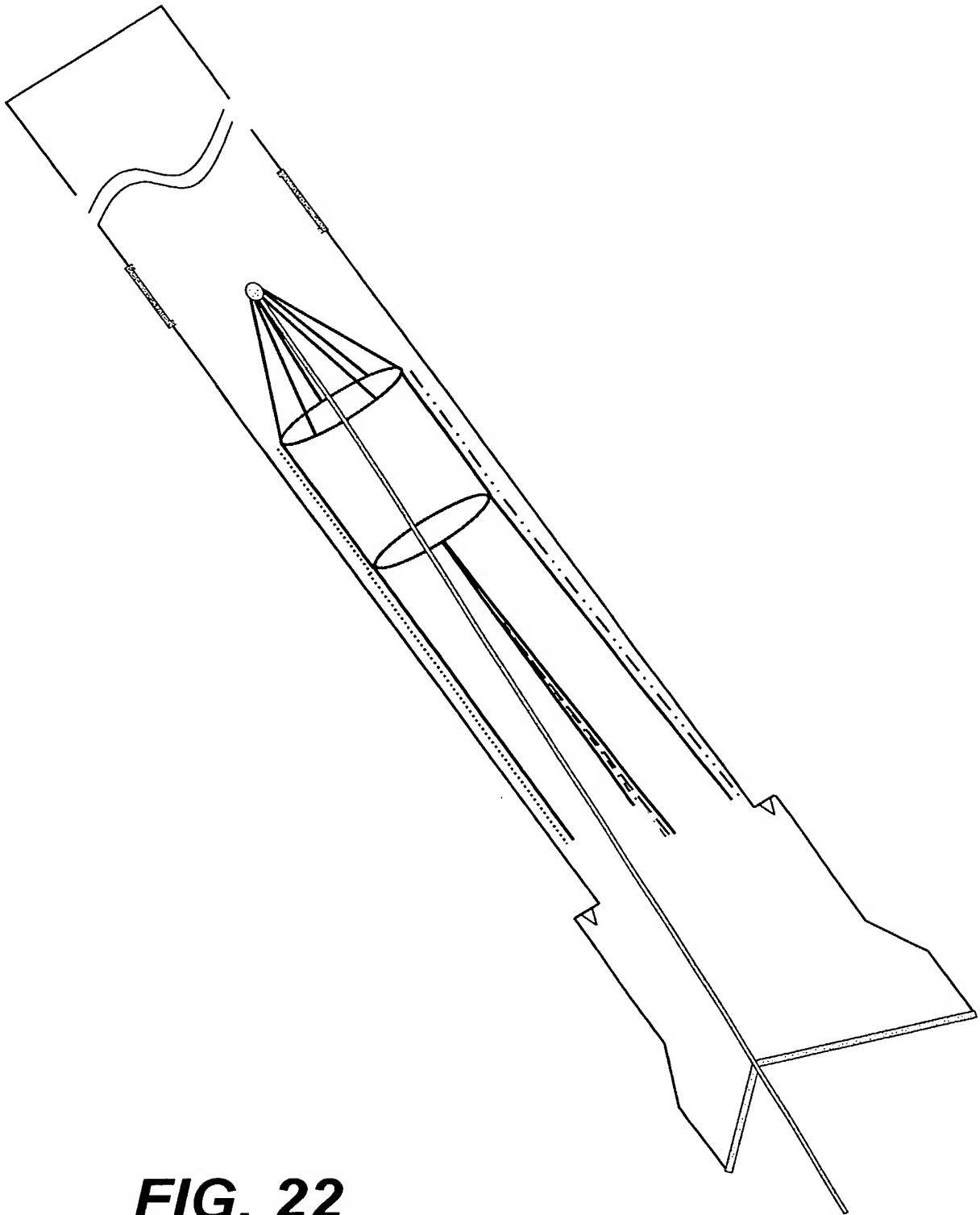


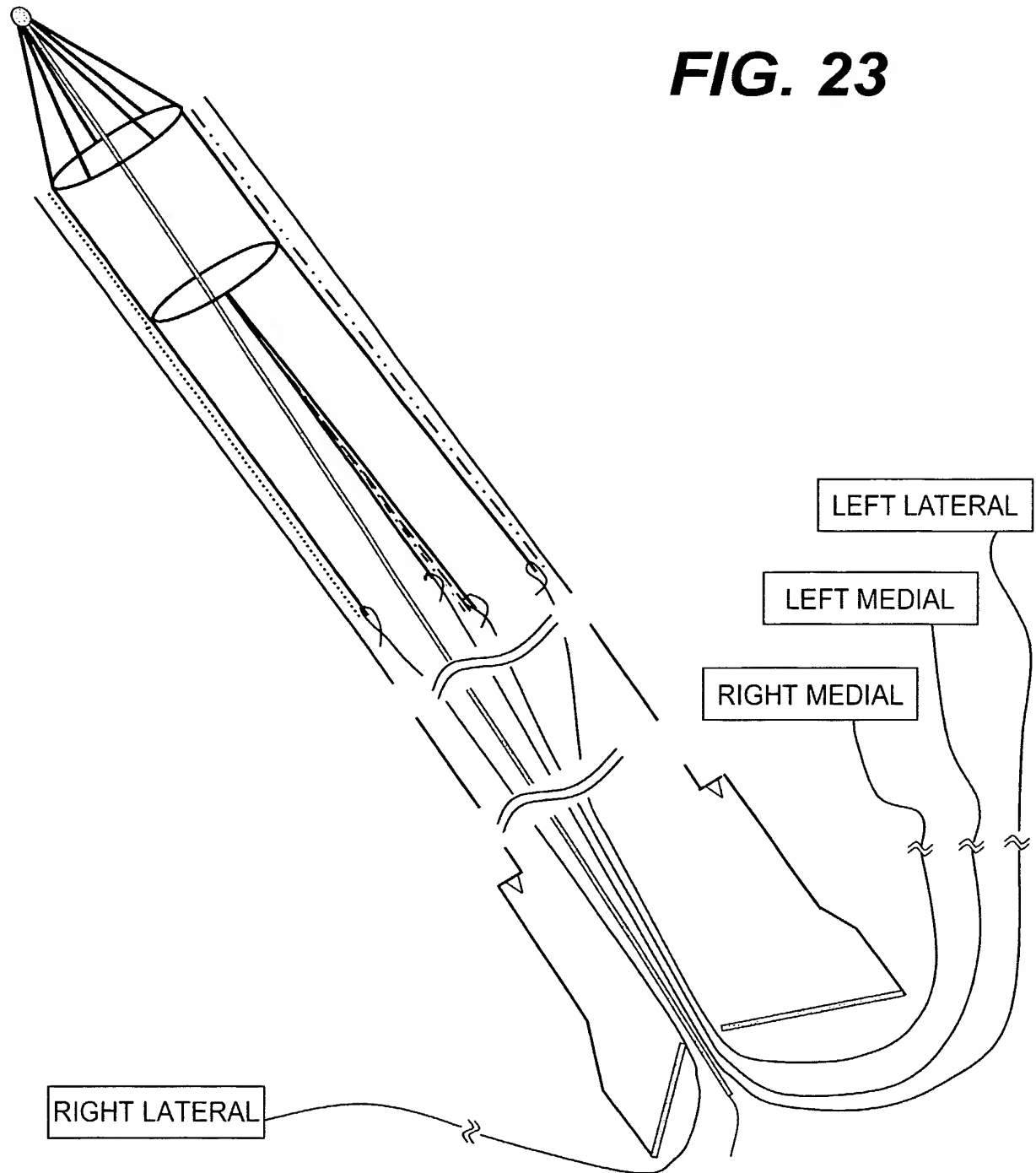
FIG. 21

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FIG. 23



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FIG. 24

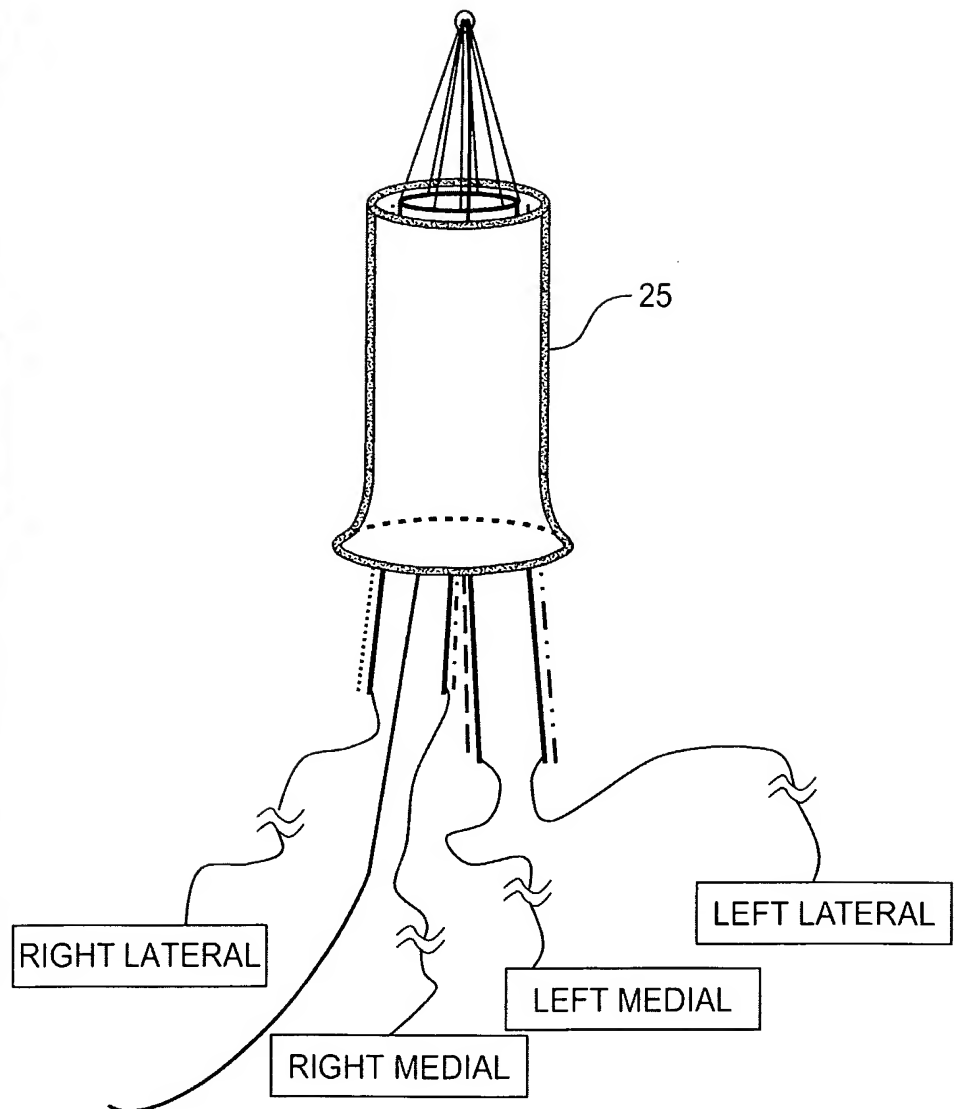
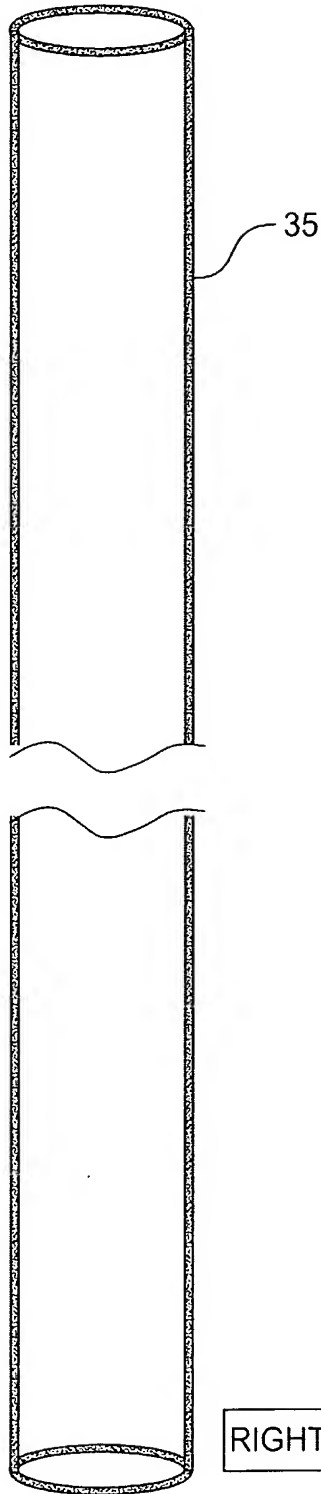
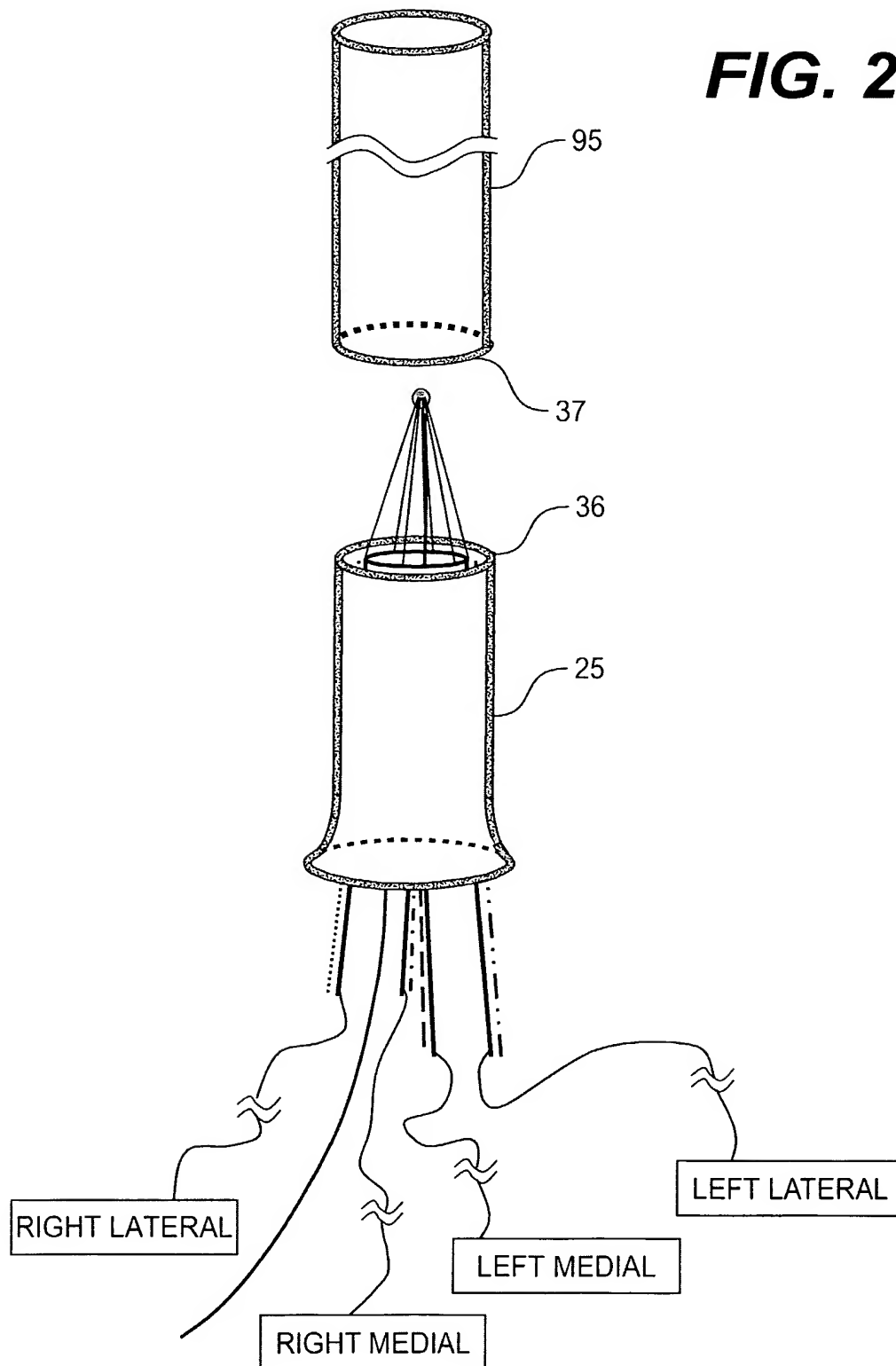
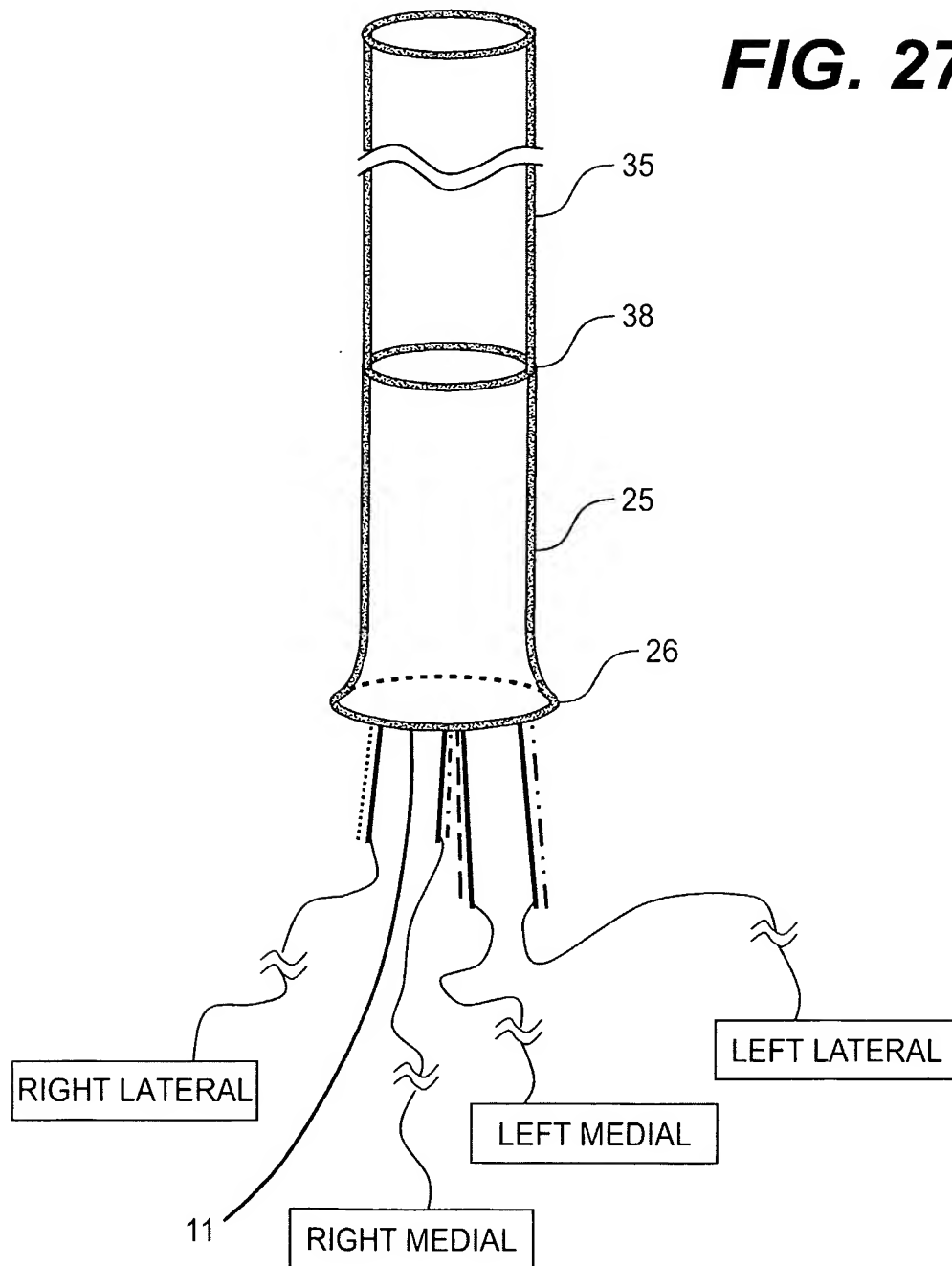


FIG. 25

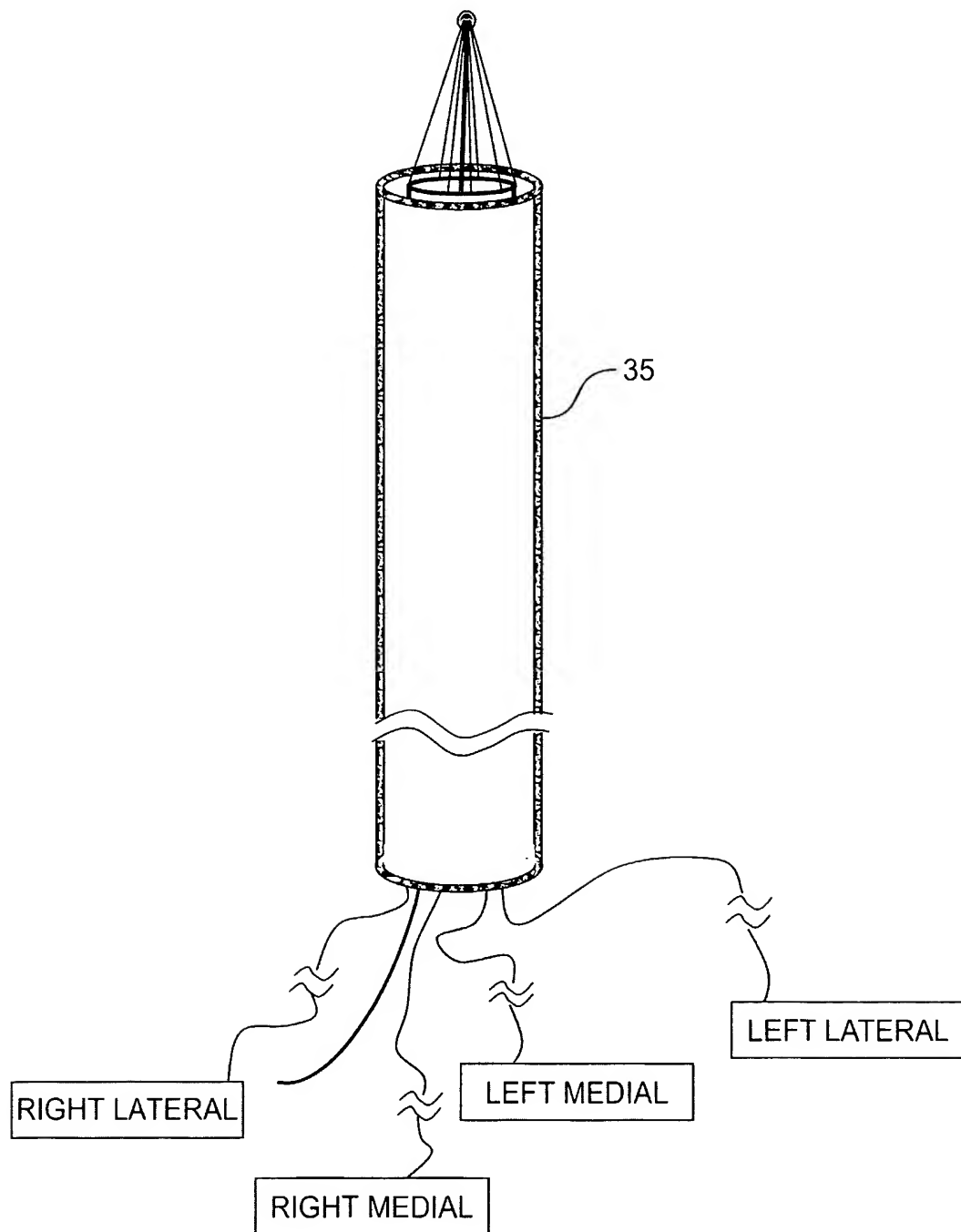
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FIG. 26

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FIG. 27

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**FIG. 28**

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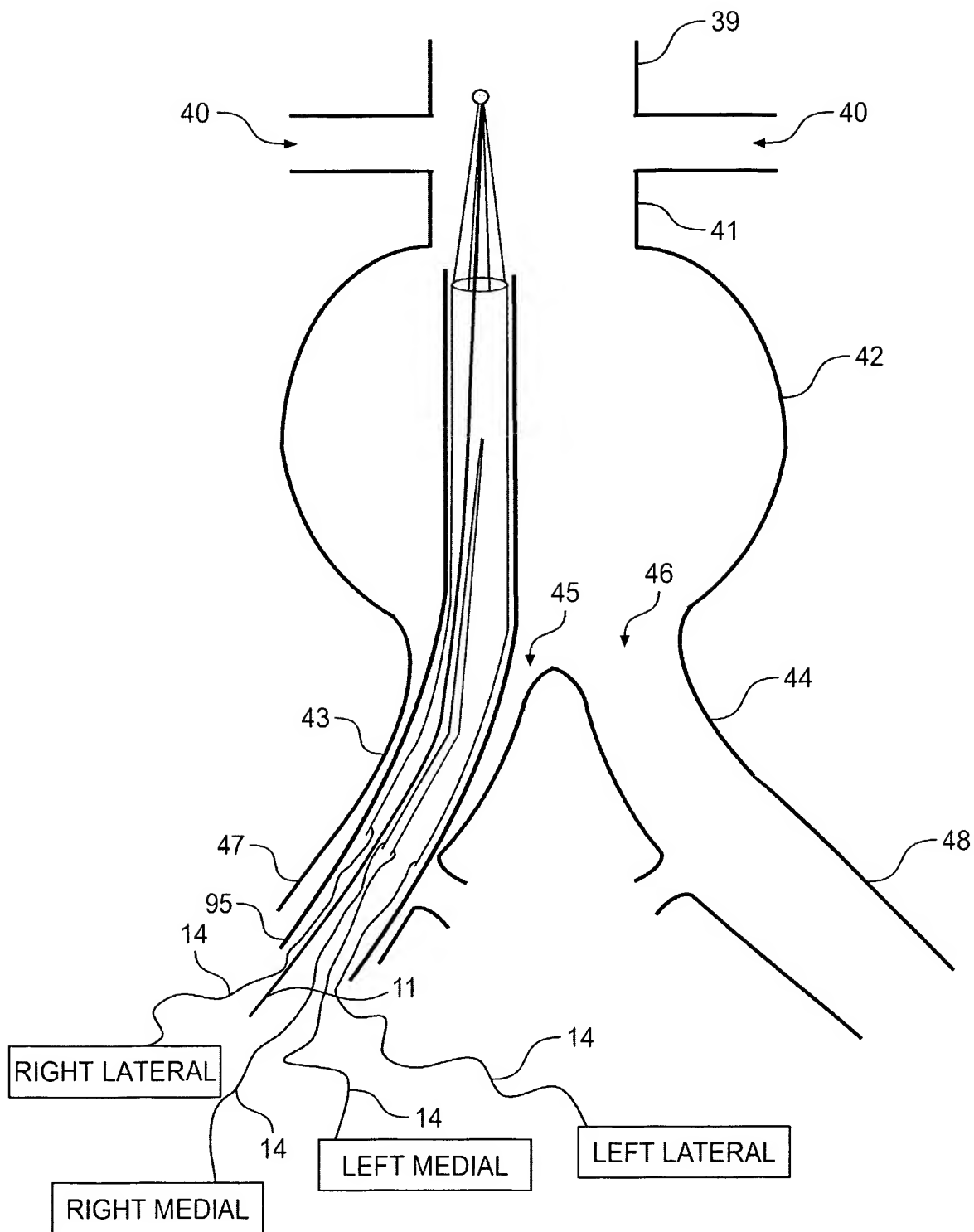


FIG. 29

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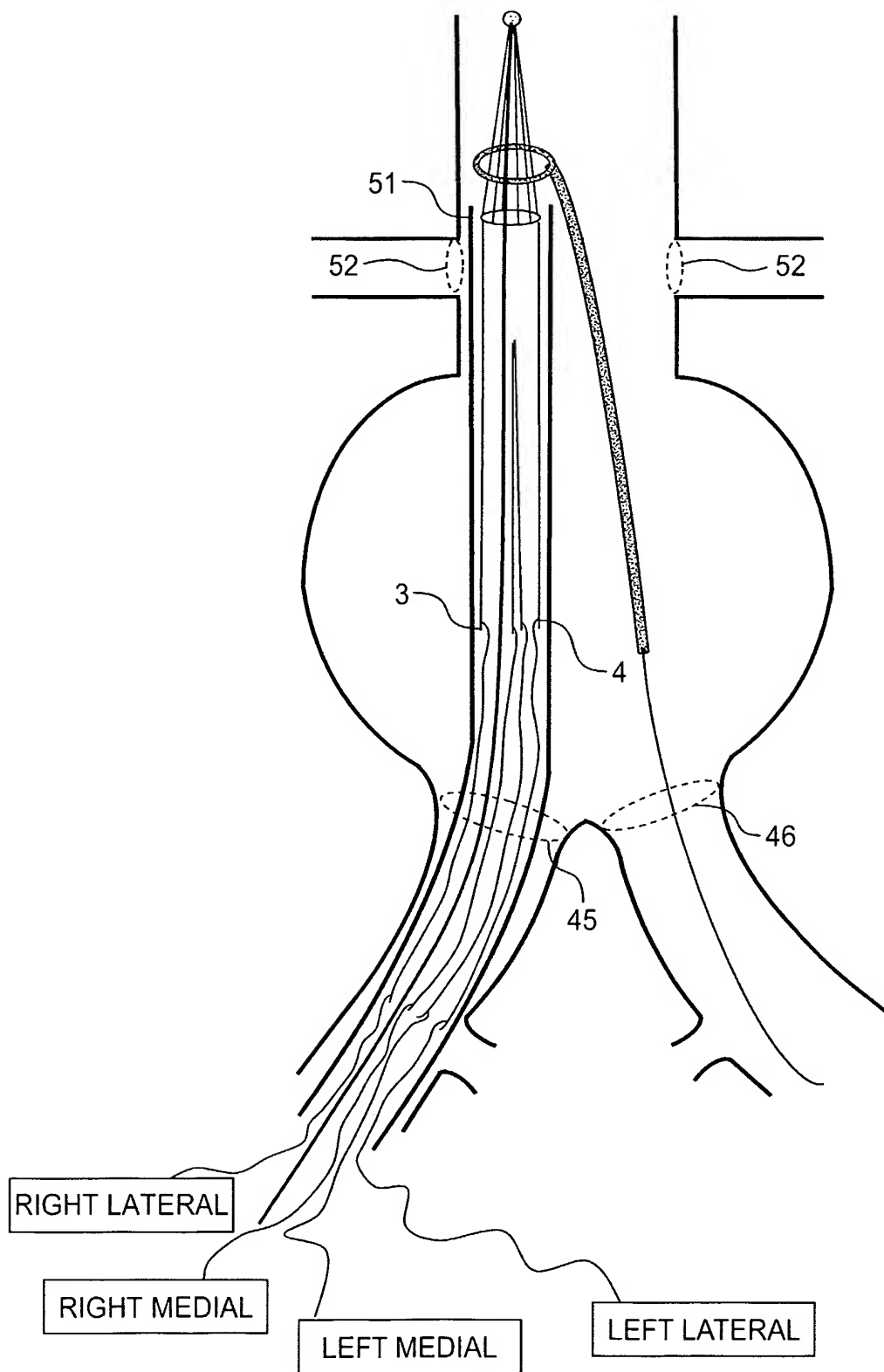


FIG. 31

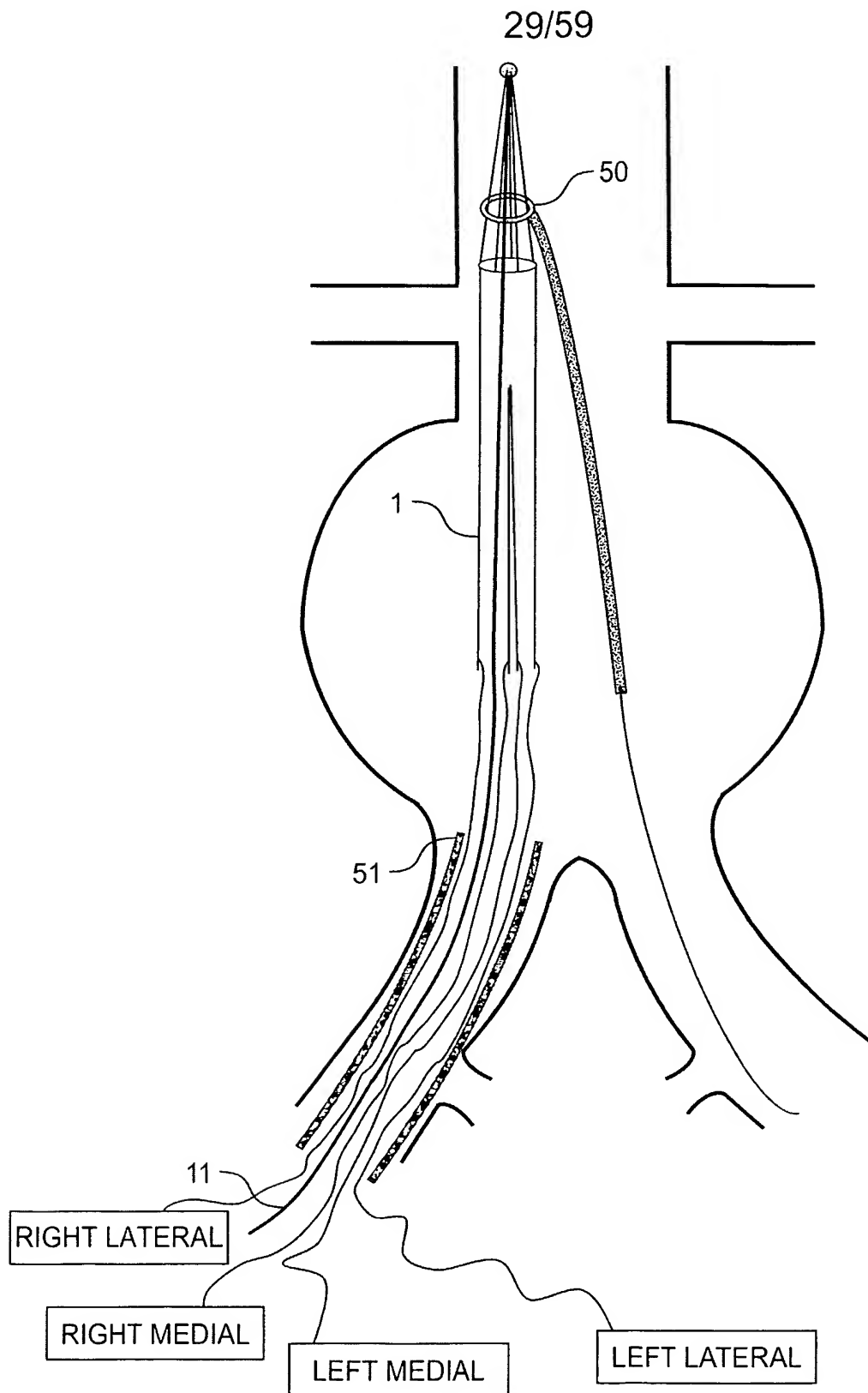


FIG. 32

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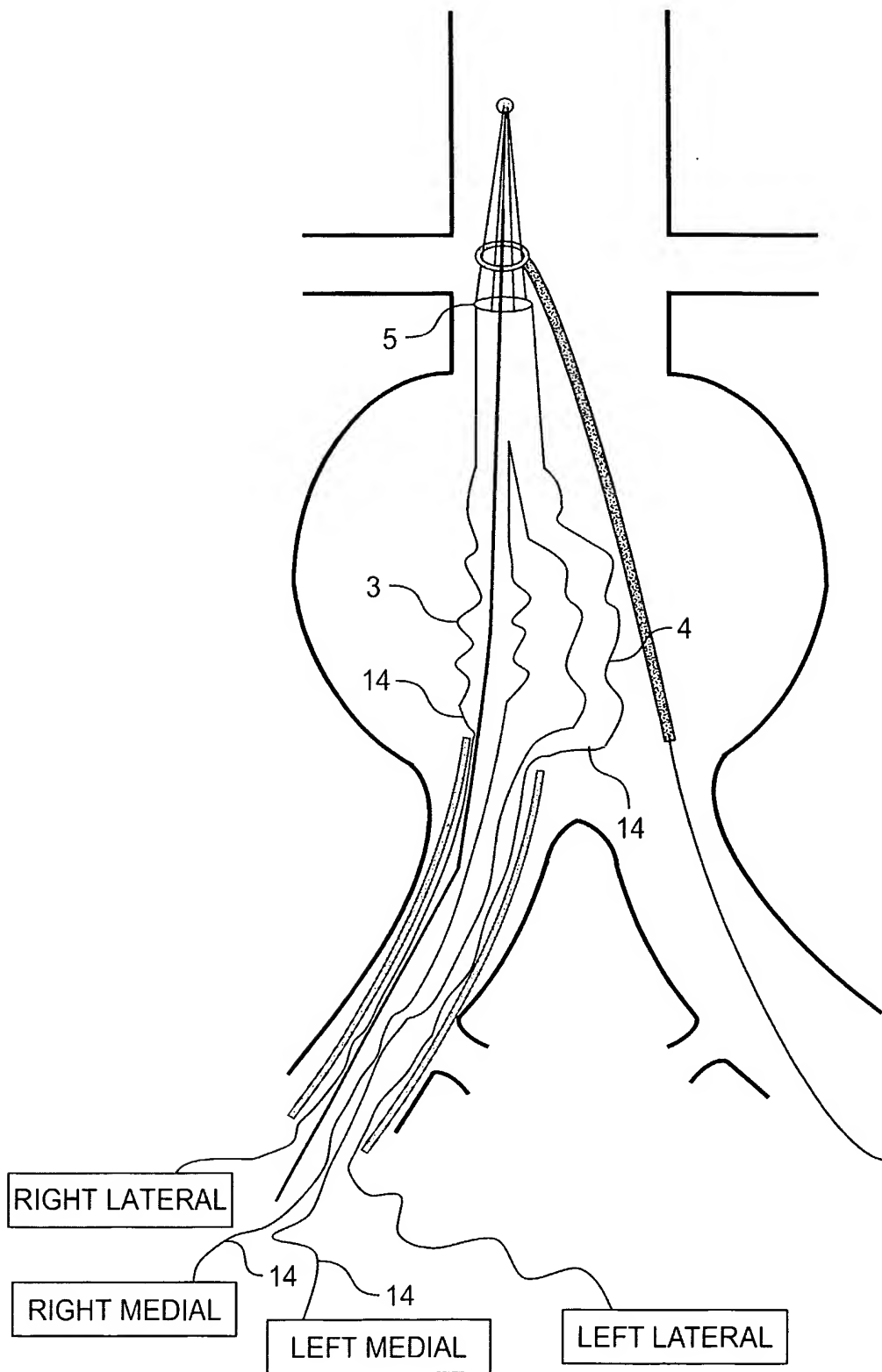


FIG. 33

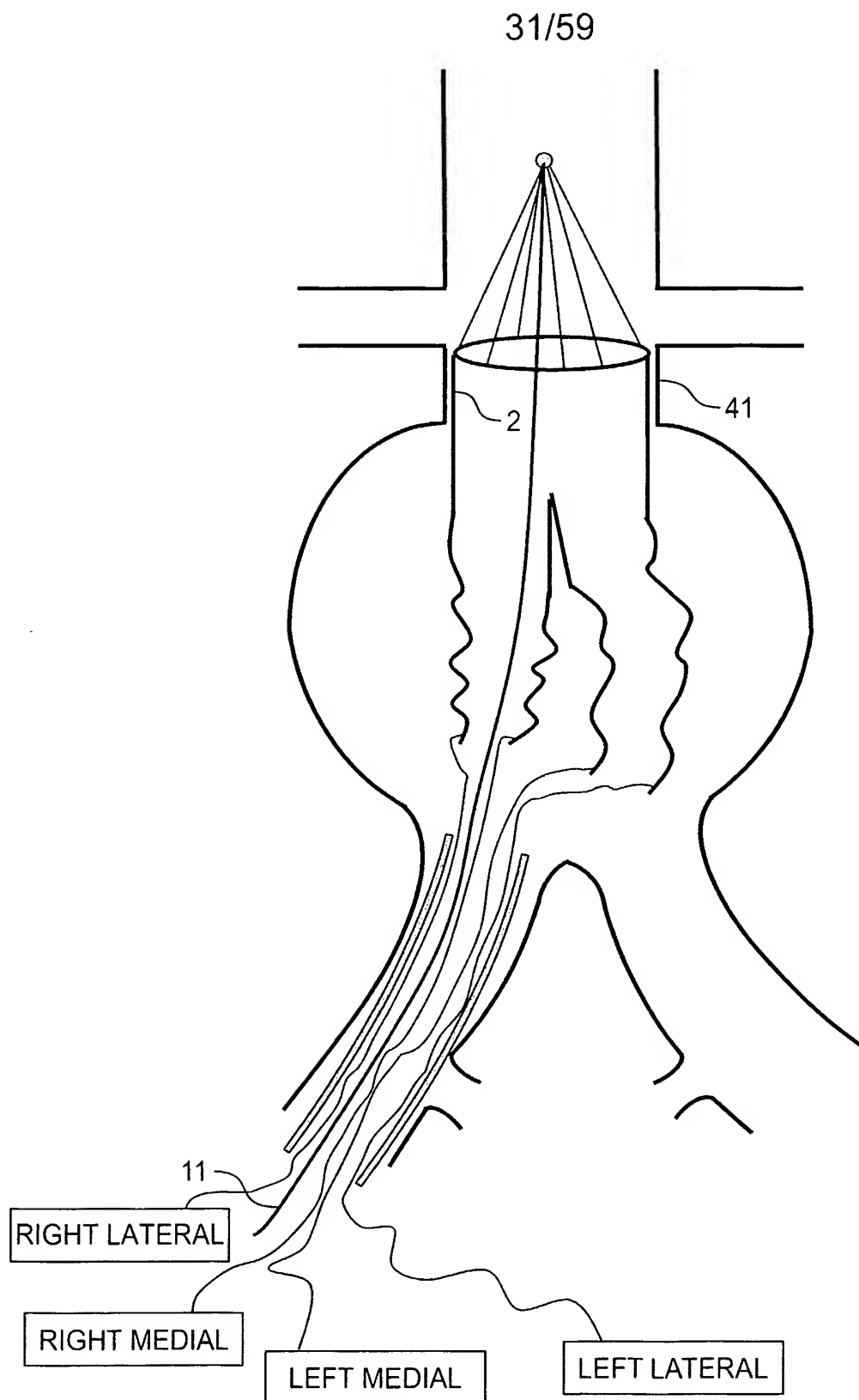


FIG. 34

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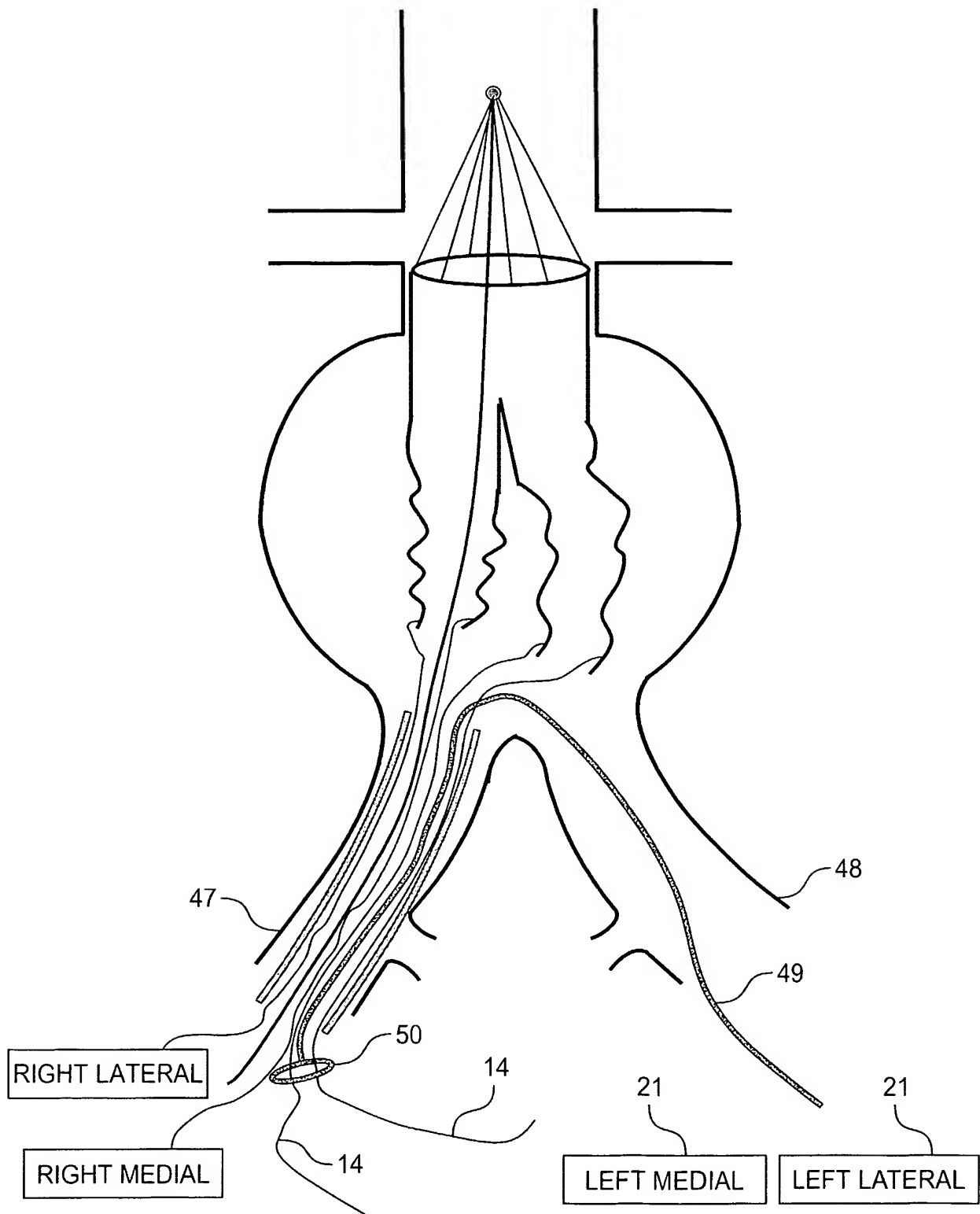


FIG. 35

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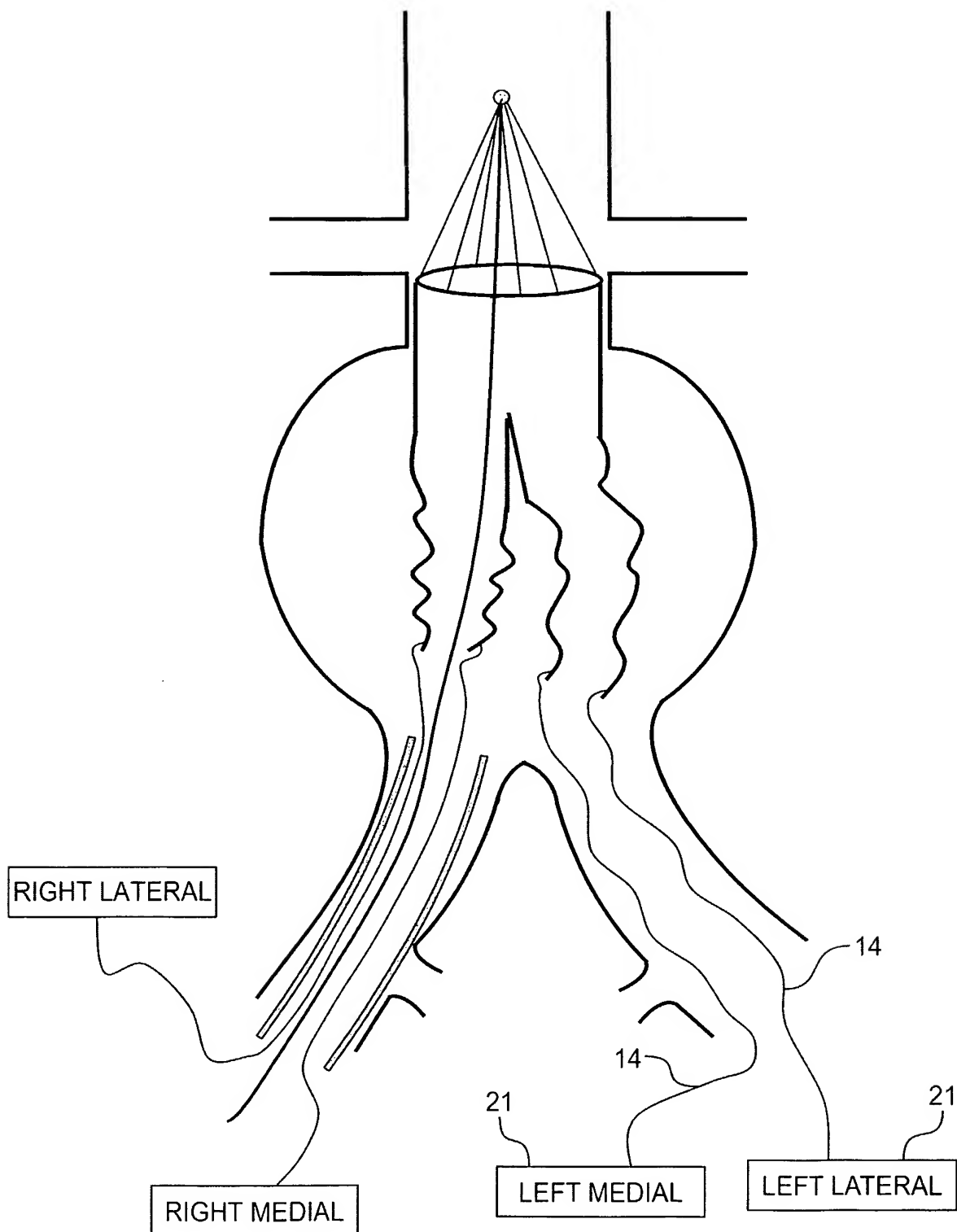


FIG. 36

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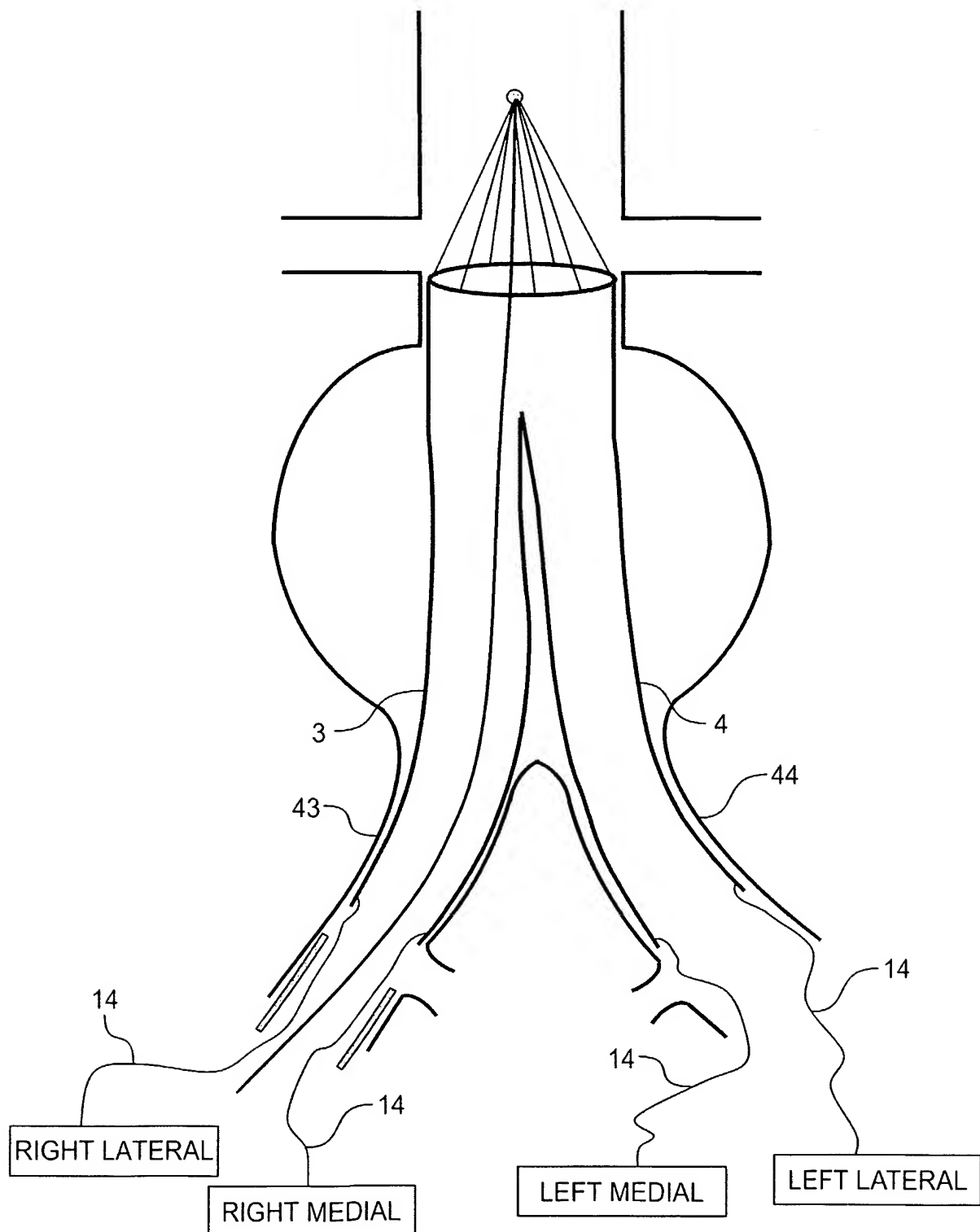


FIG. 37

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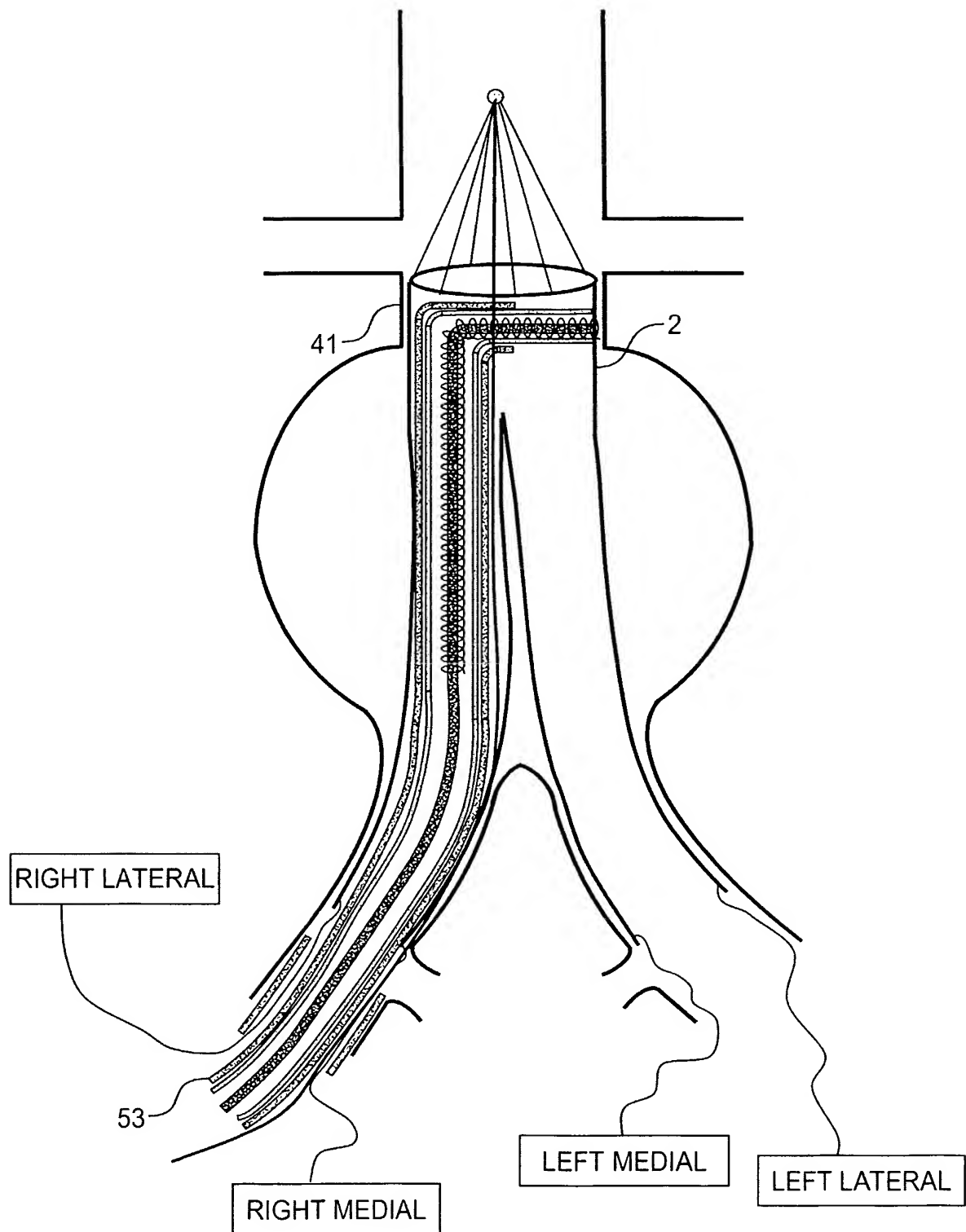
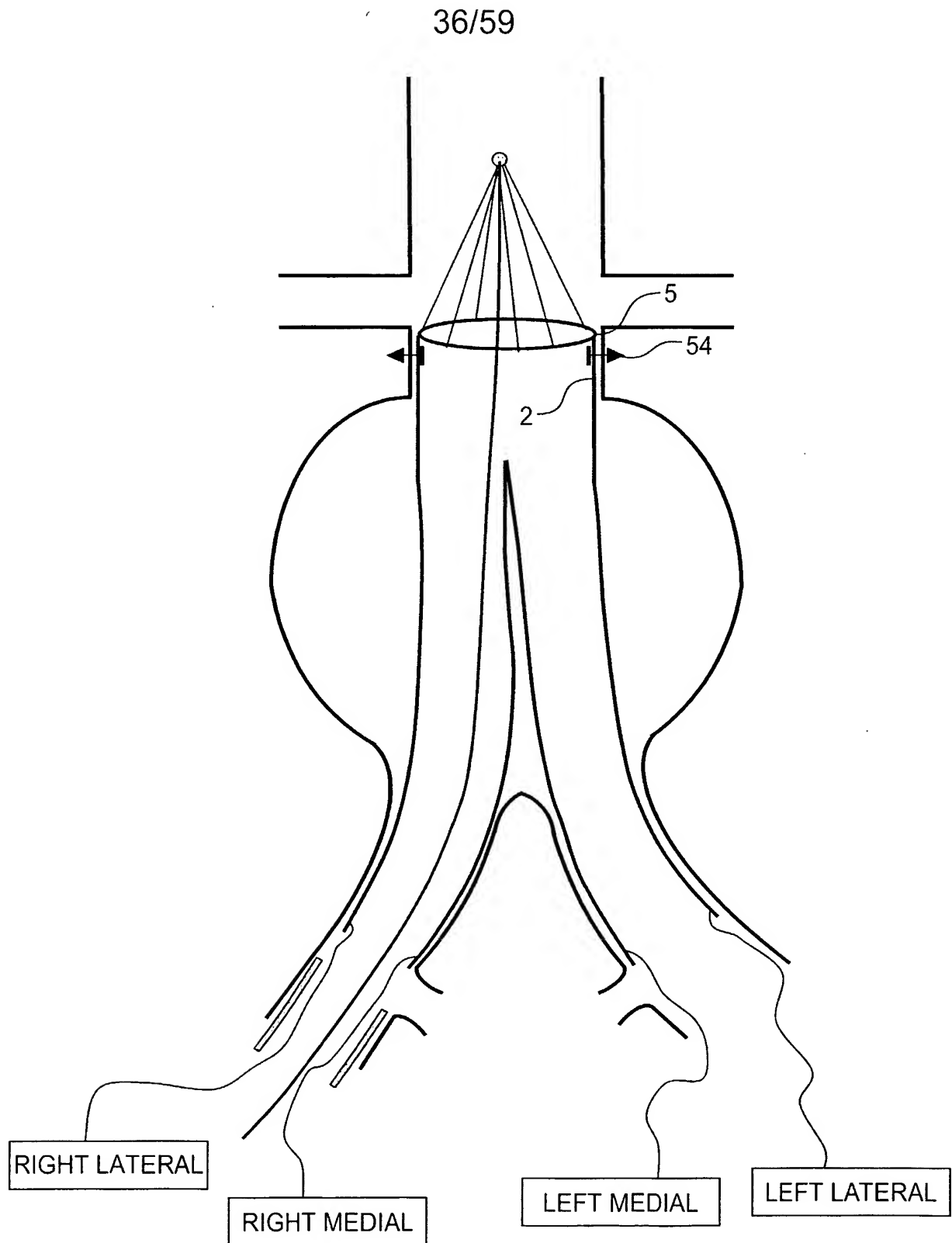


FIG. 38

**FIG. 39**

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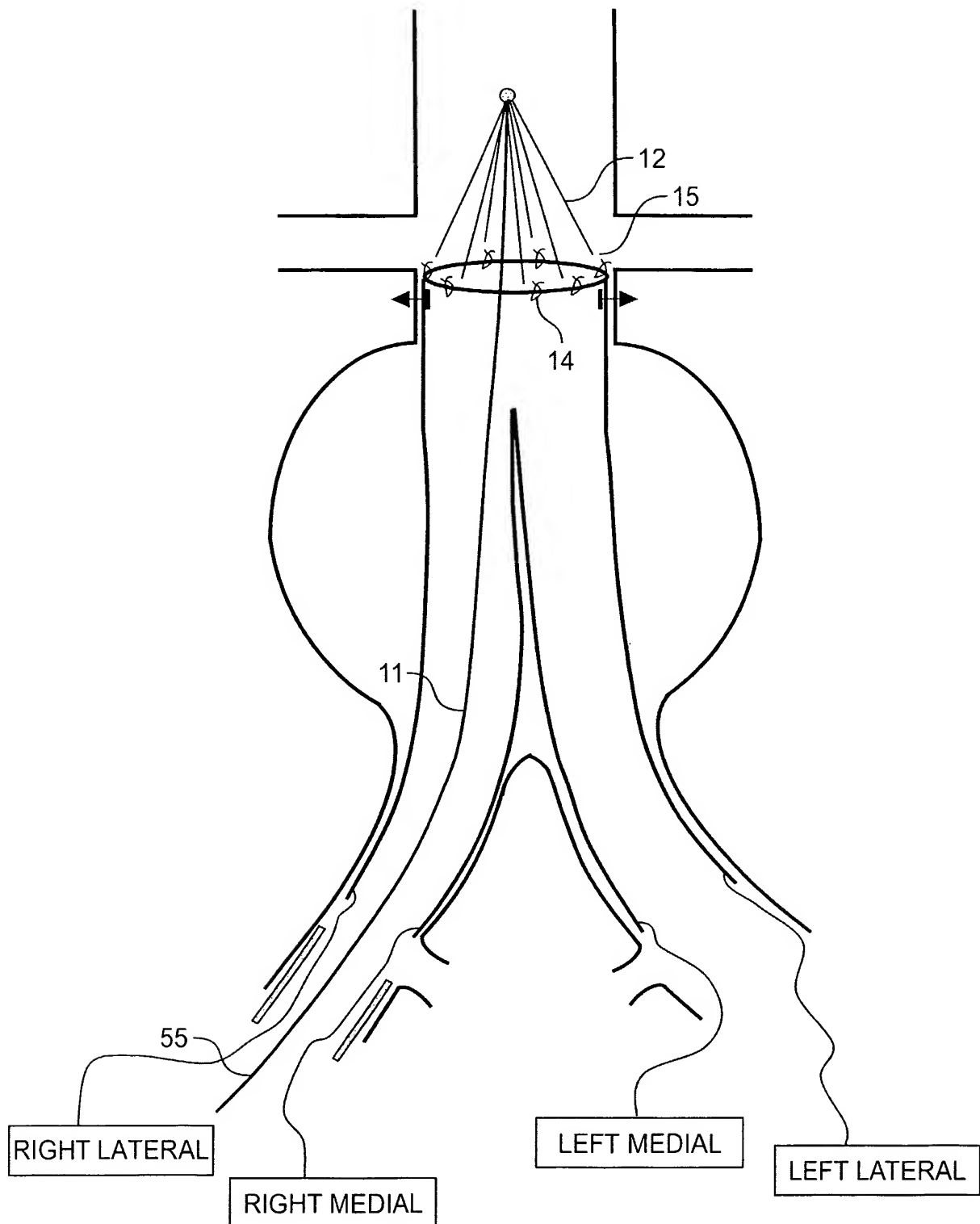


FIG. 40

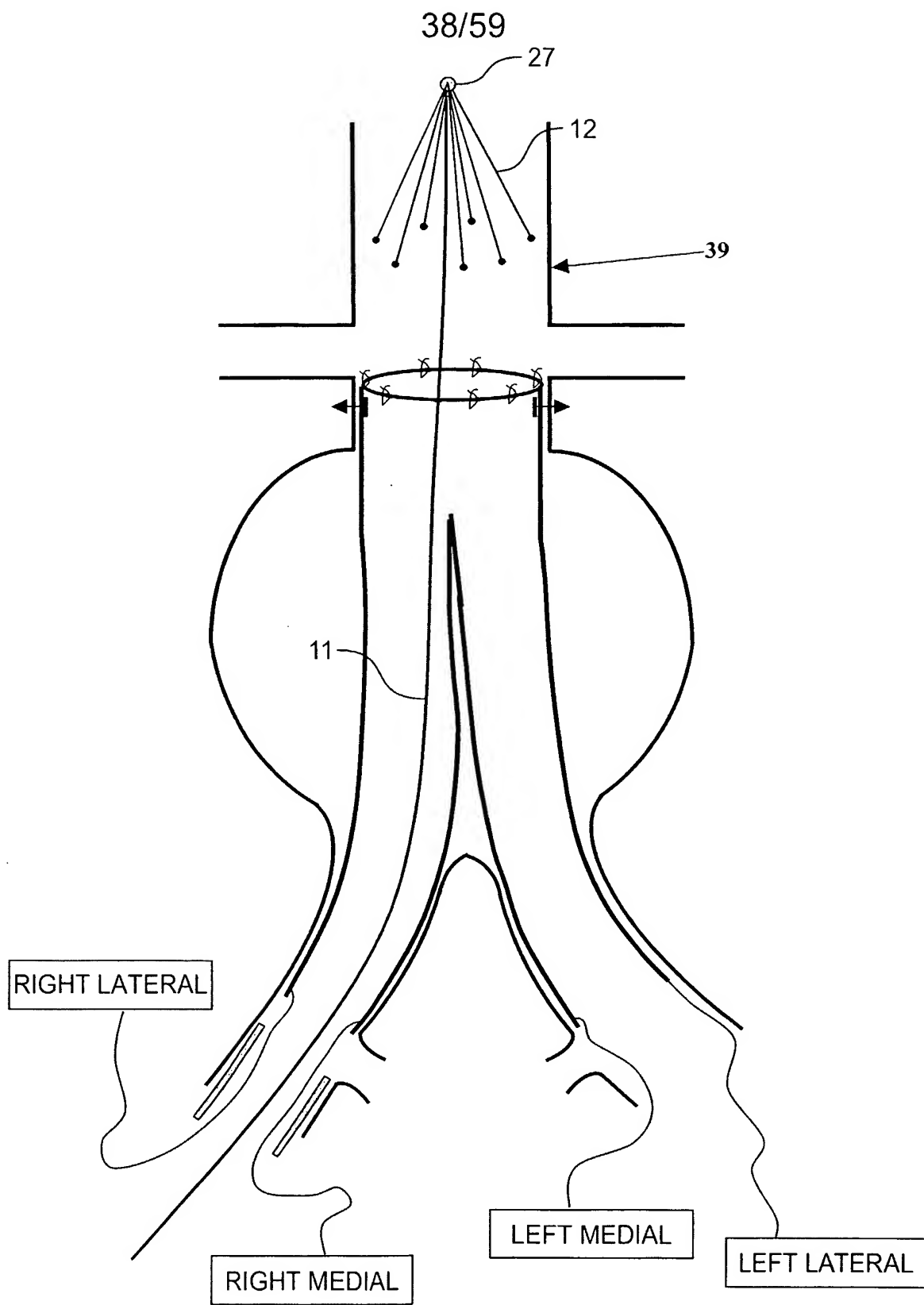


FIG. 41

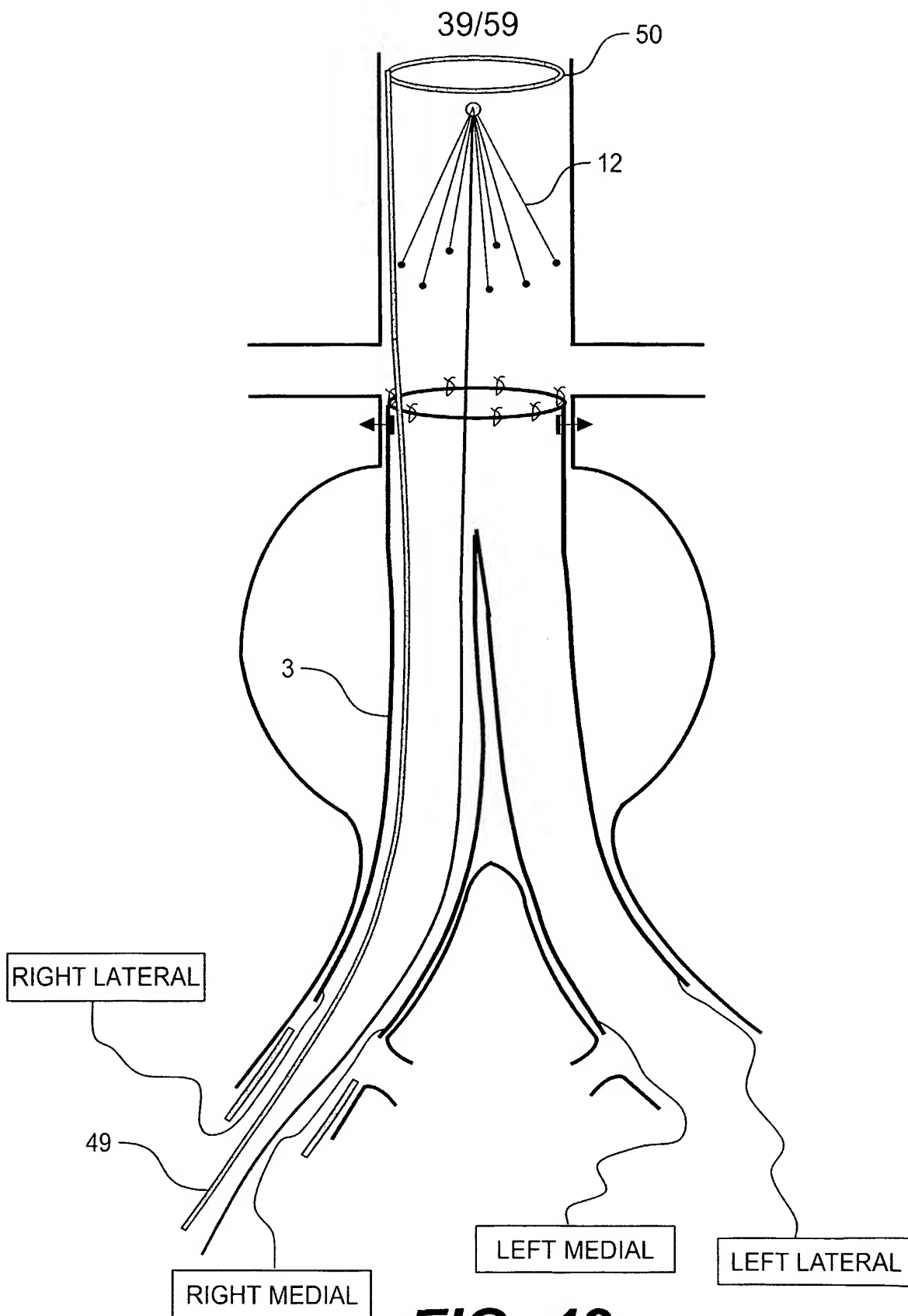


FIG. 42

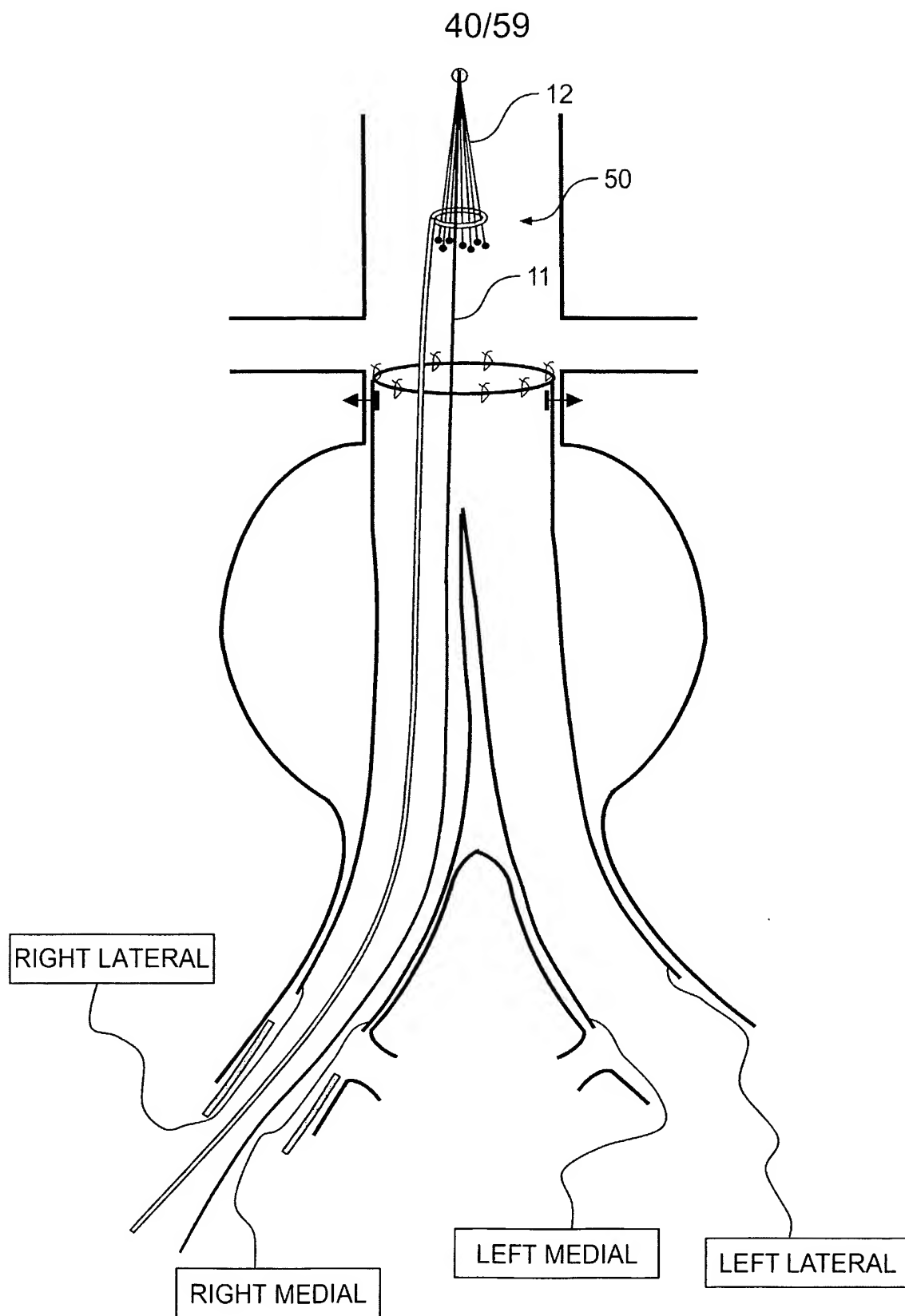
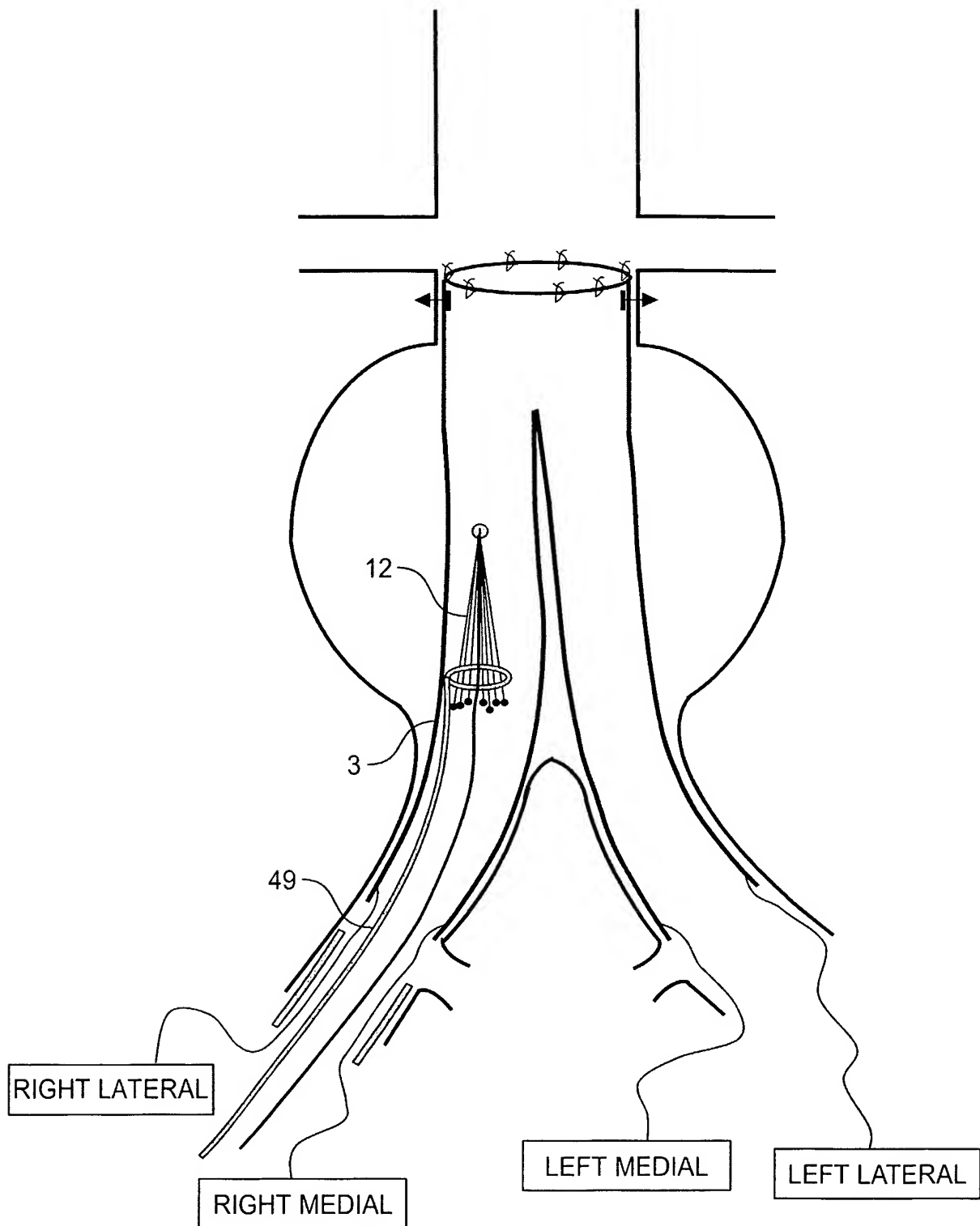


FIG. 43

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**FIG. 44**

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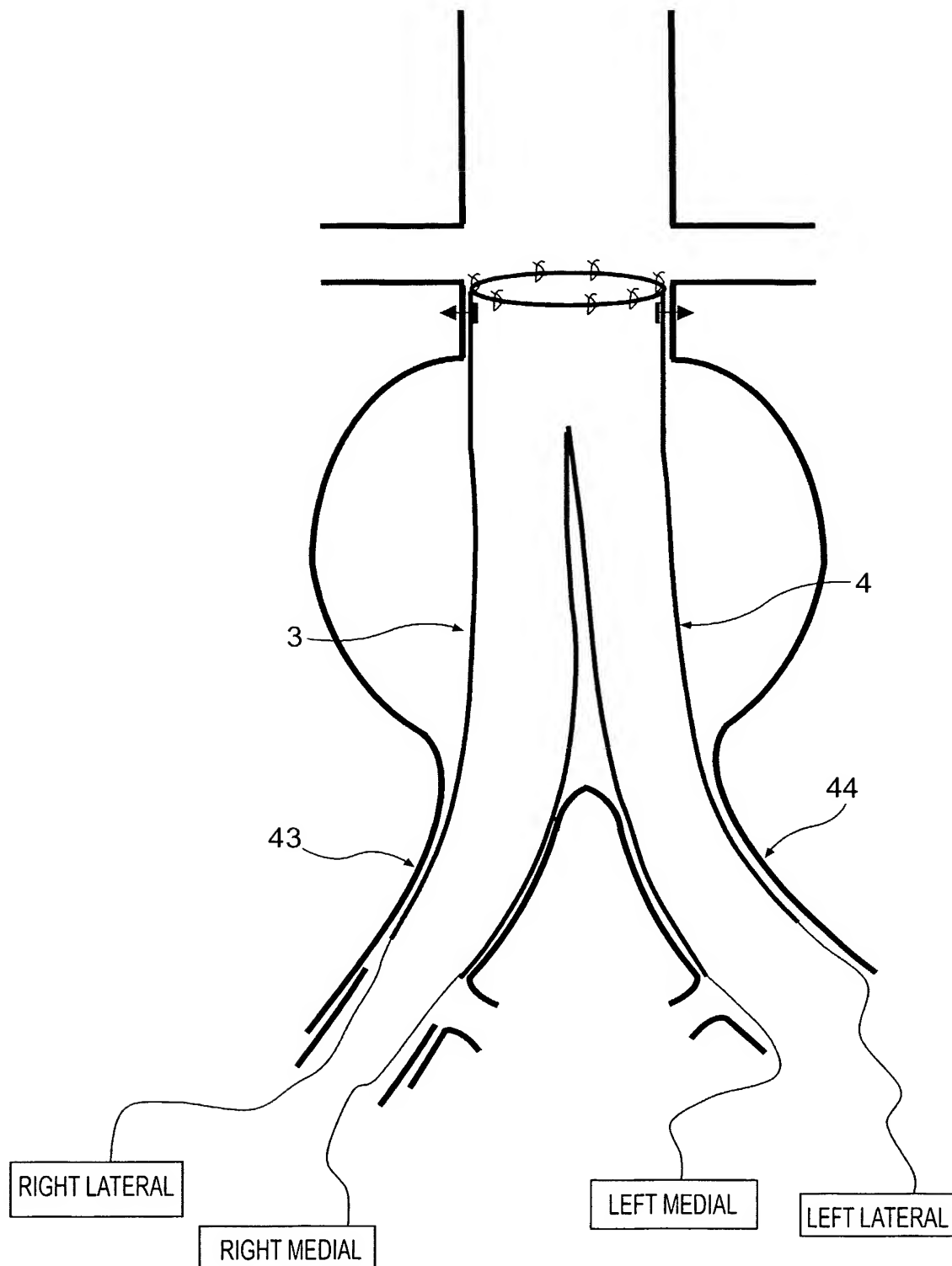


FIG. 45

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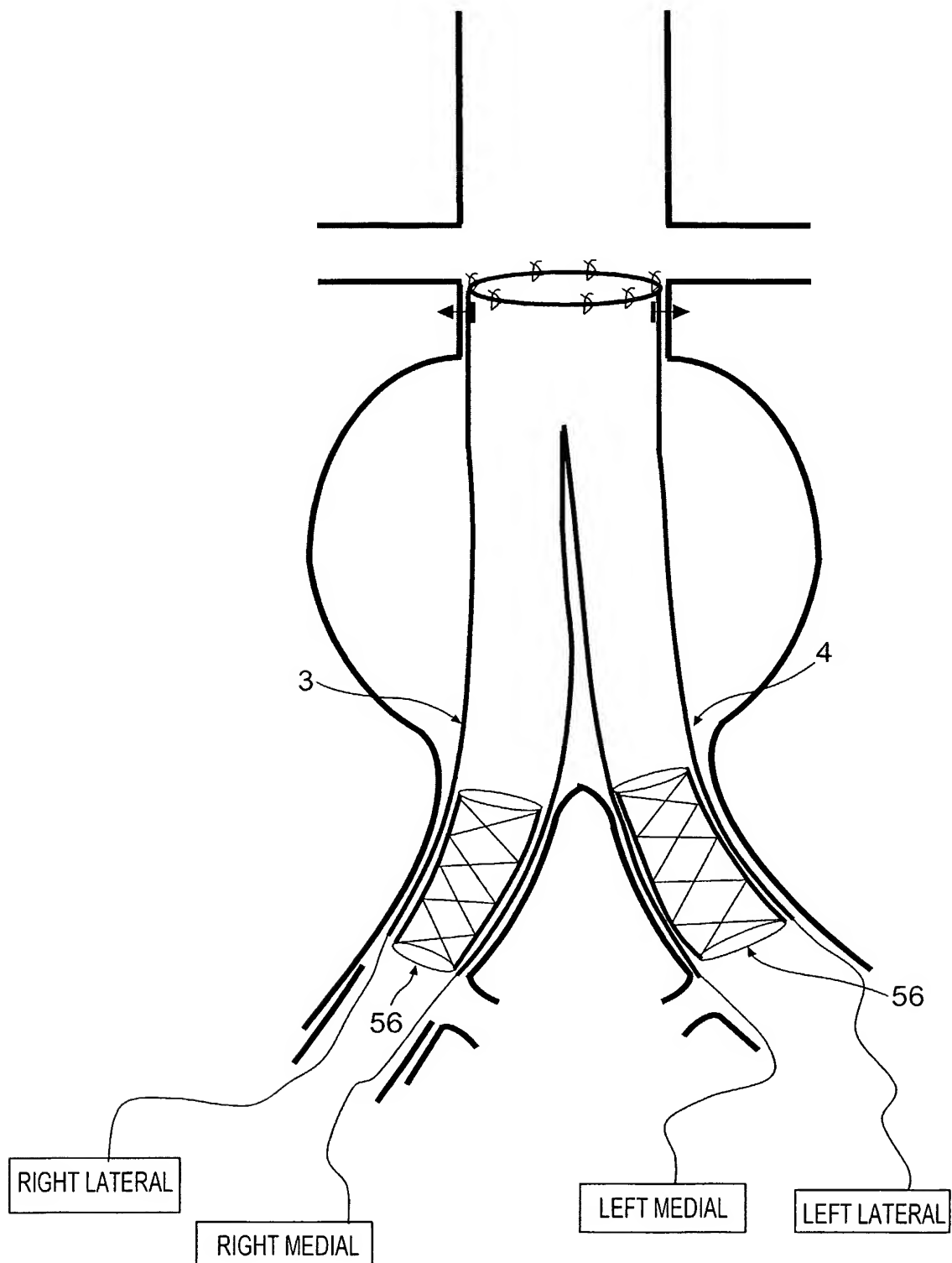
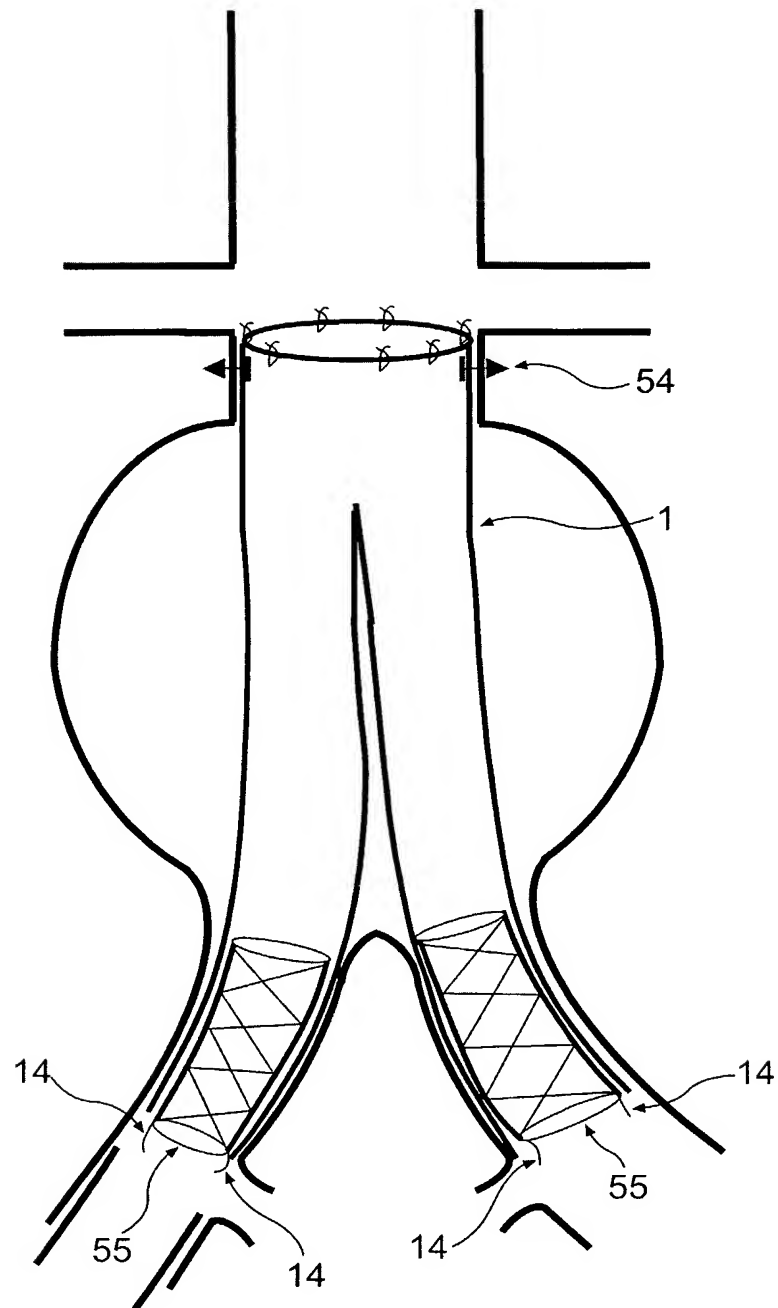


FIG. 46

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**FIG. 47**

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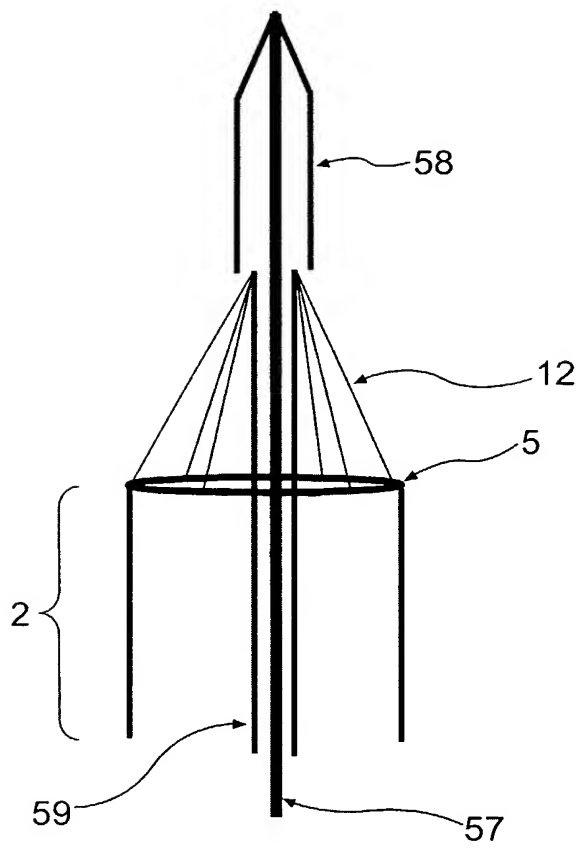


FIG. 48

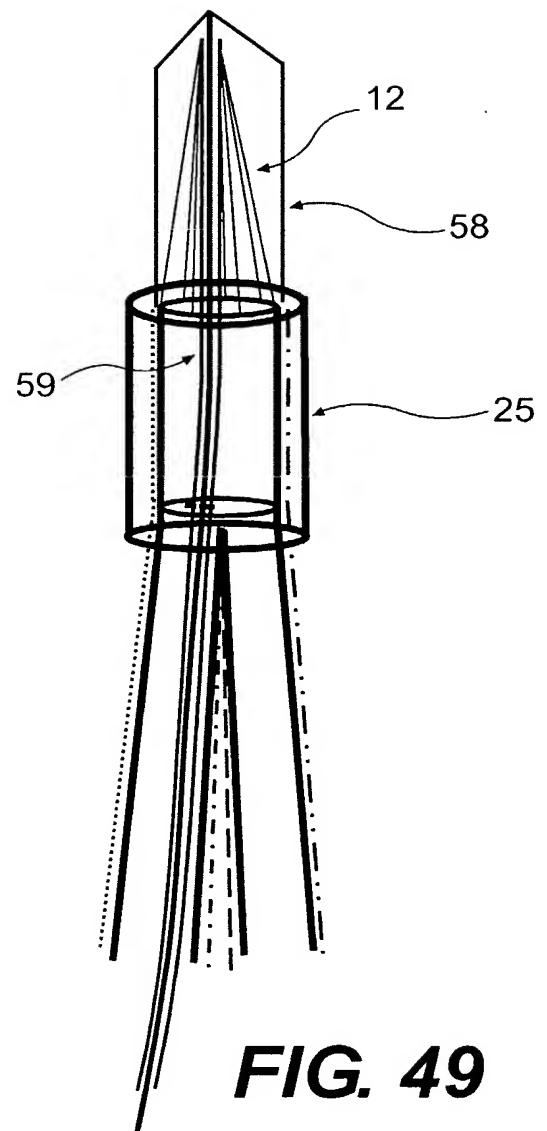


FIG. 49

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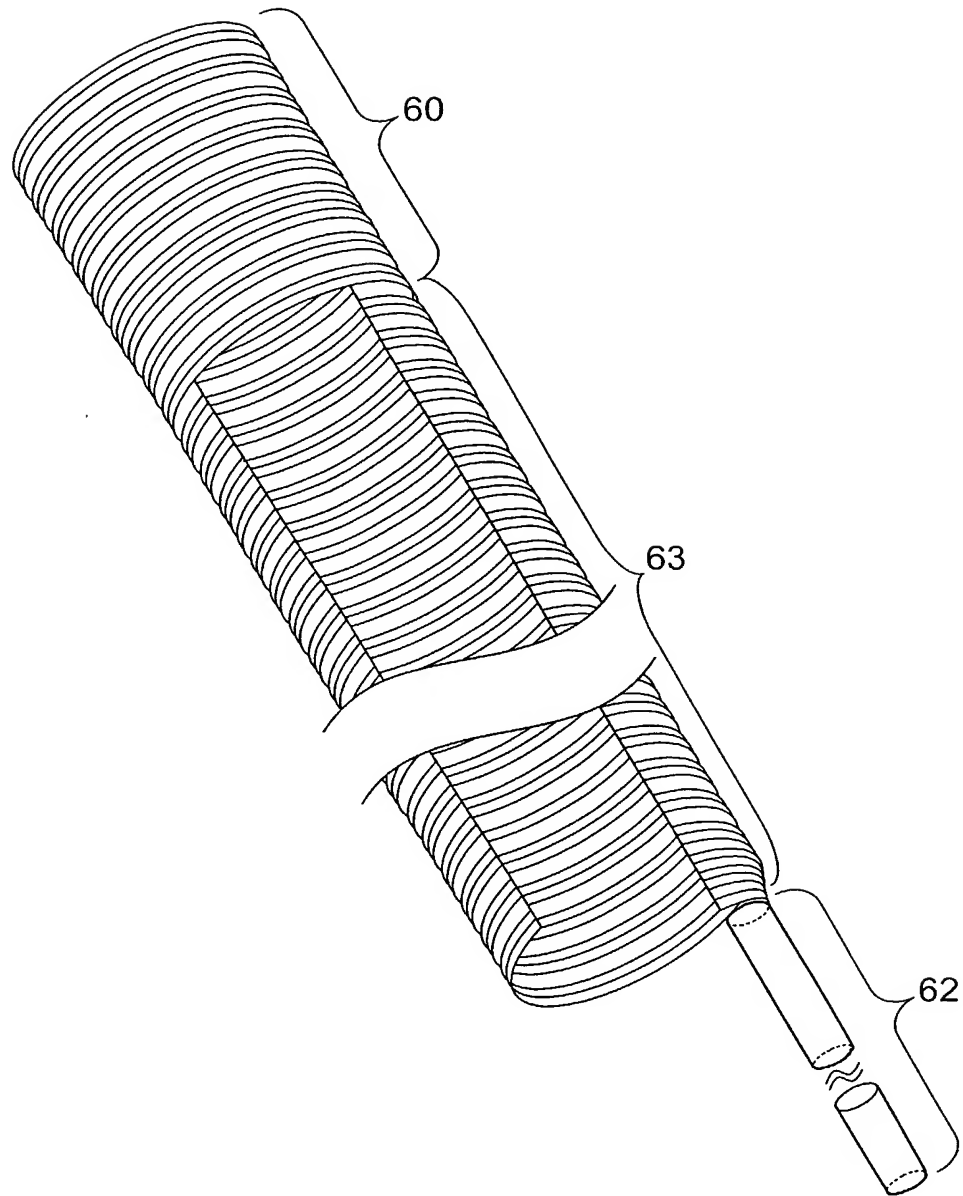


FIG. 50

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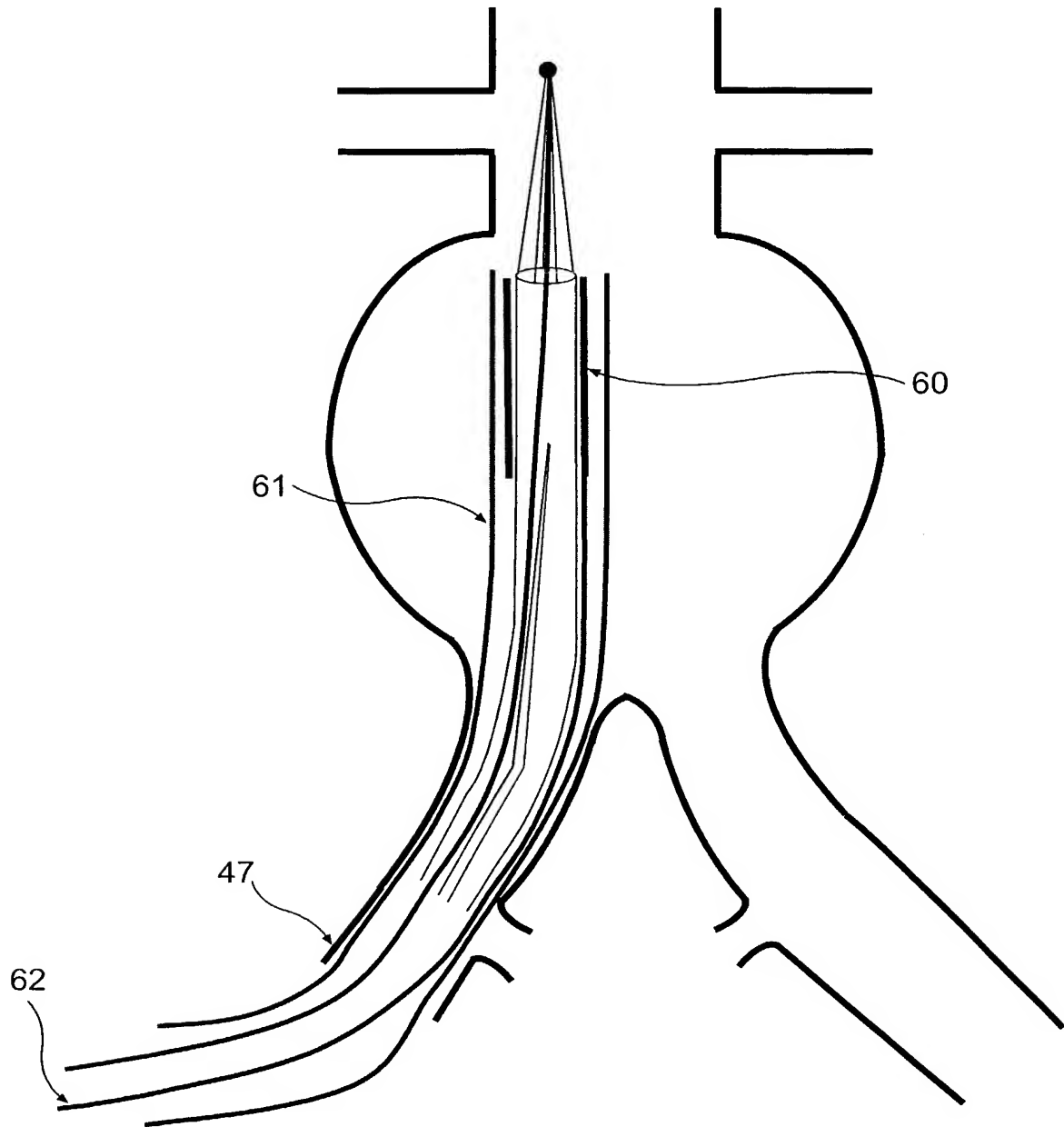


FIG. 51

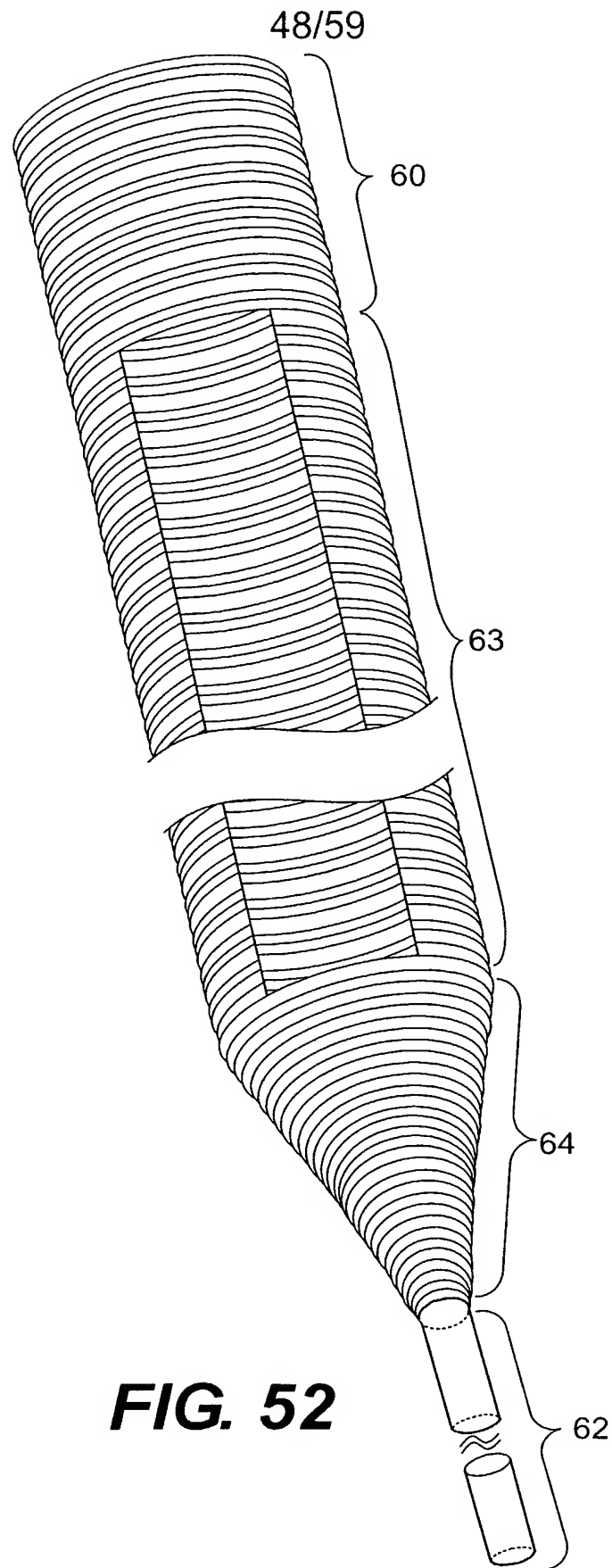


FIG. 52

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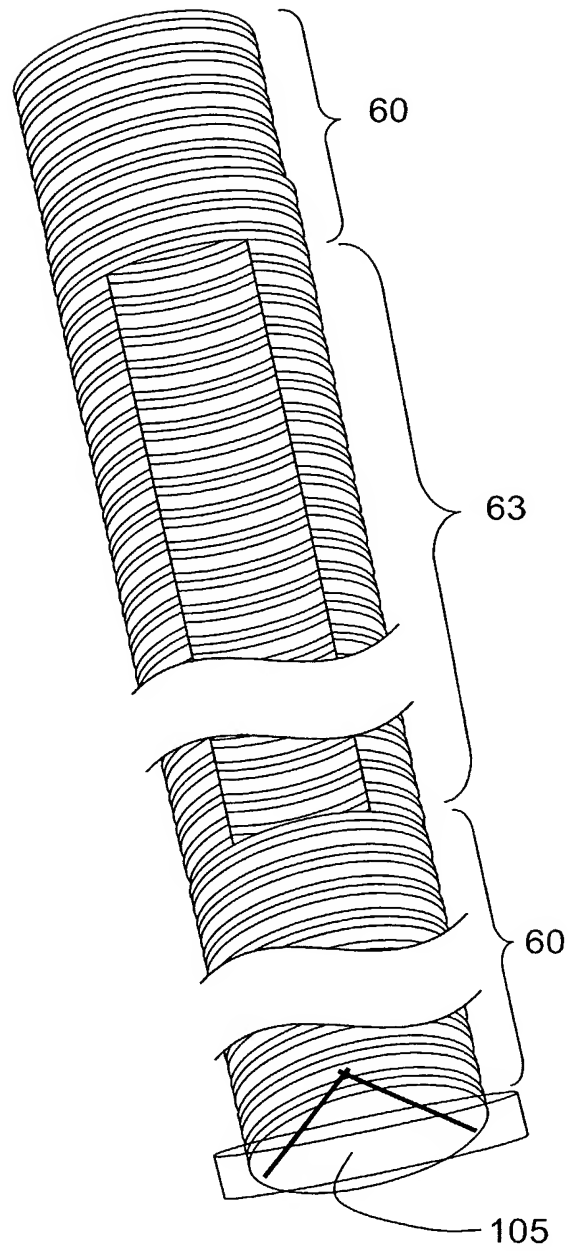


FIG. 53

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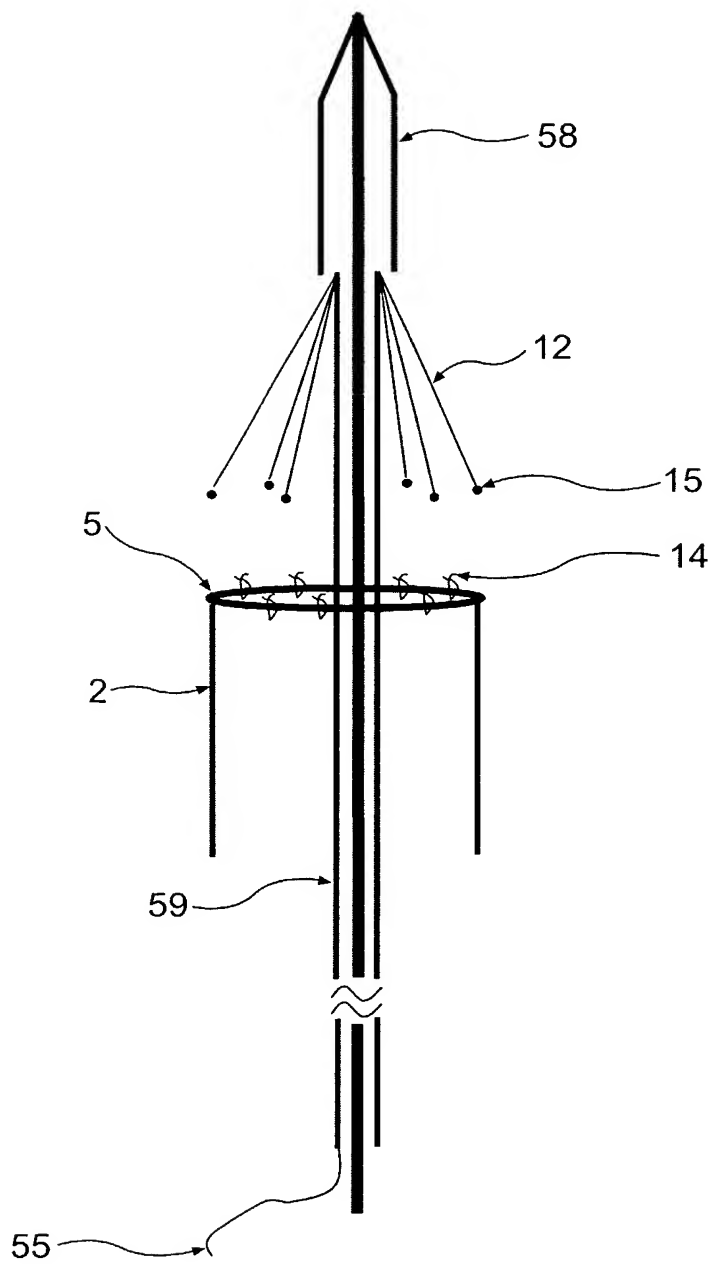


FIG. 54

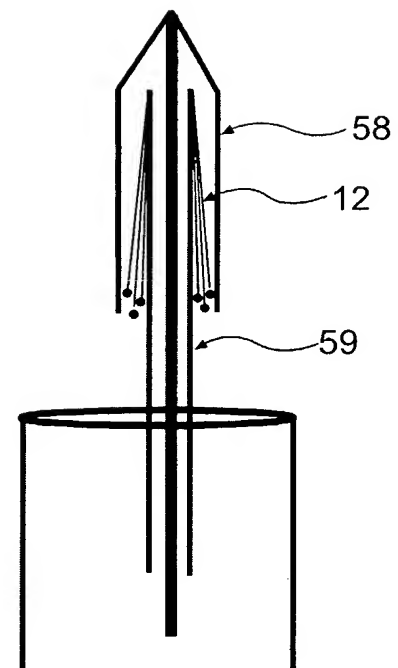


FIG. 55

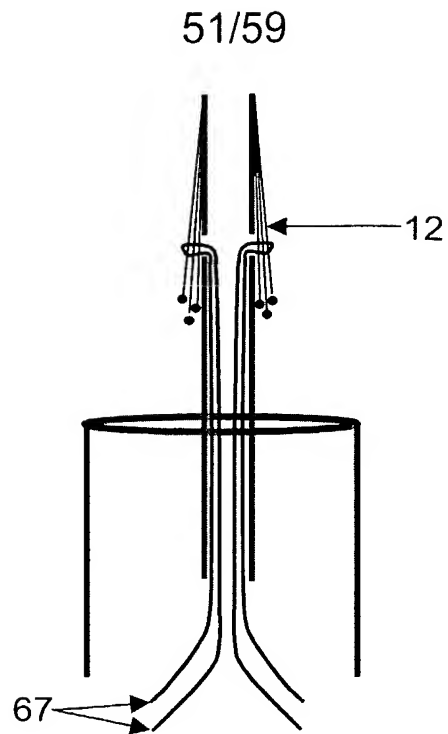


FIG. 56

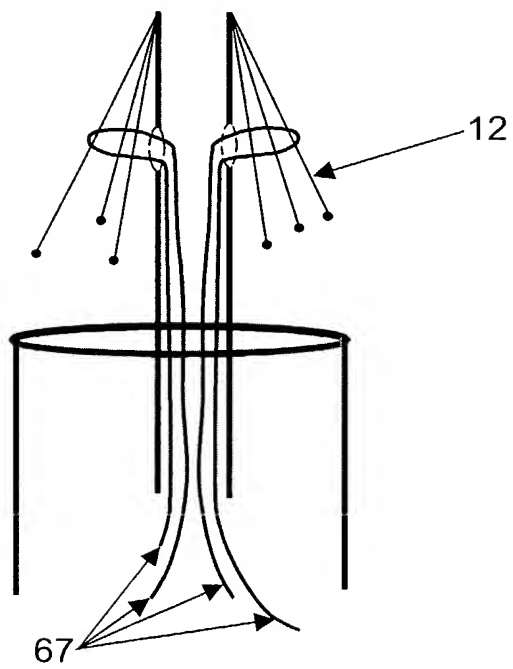
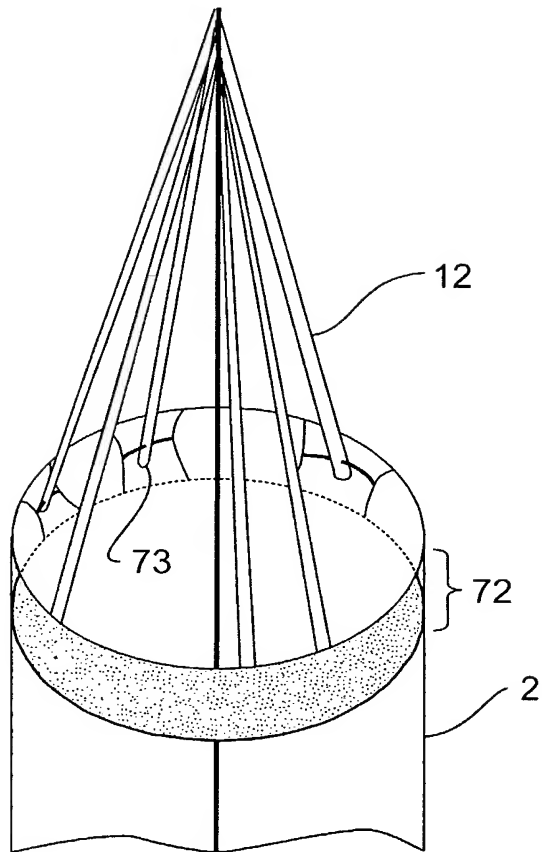


FIG. 57

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**FIG. 58**

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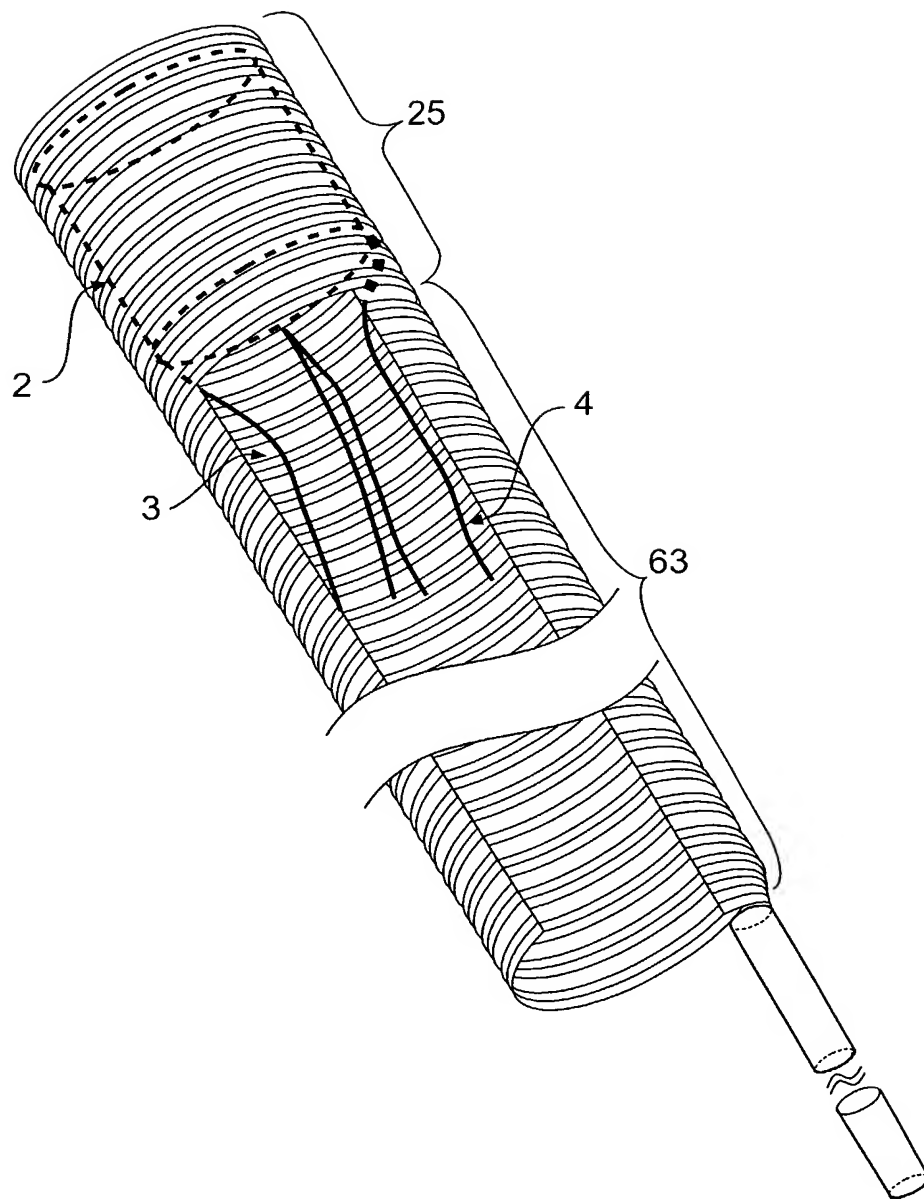


FIG. 59

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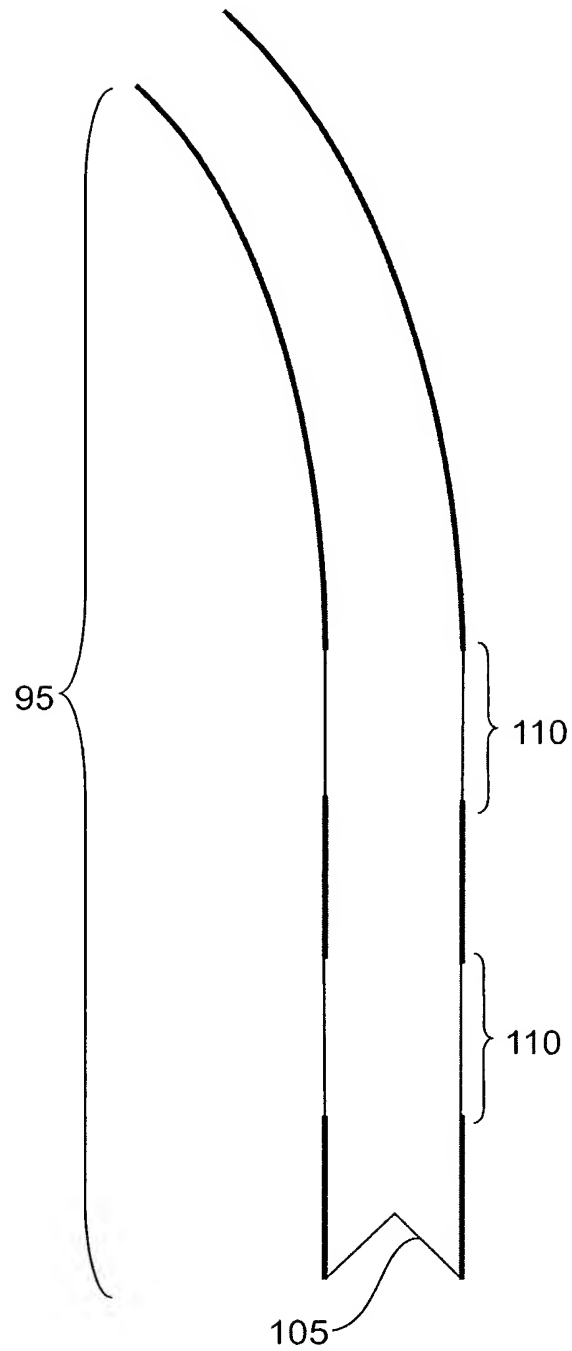
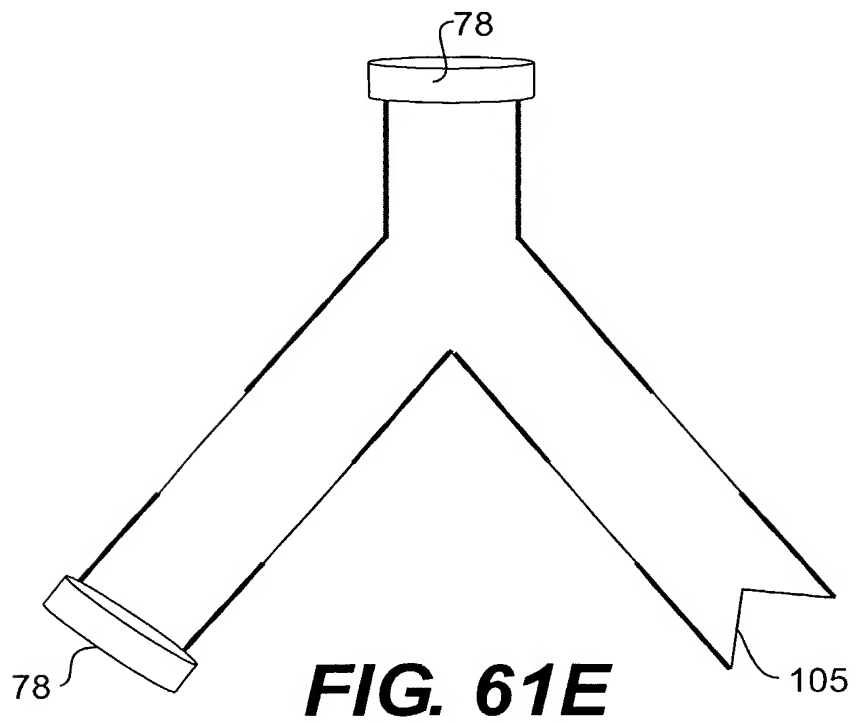
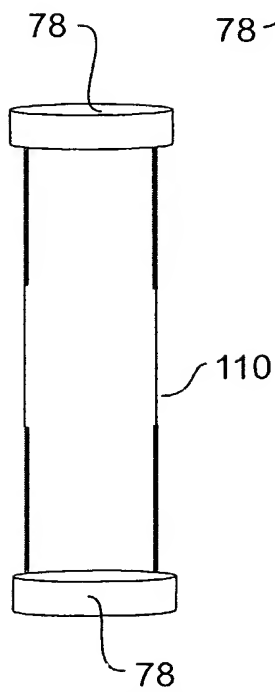
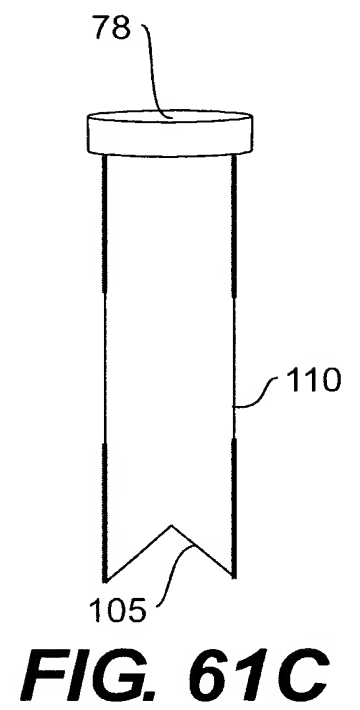
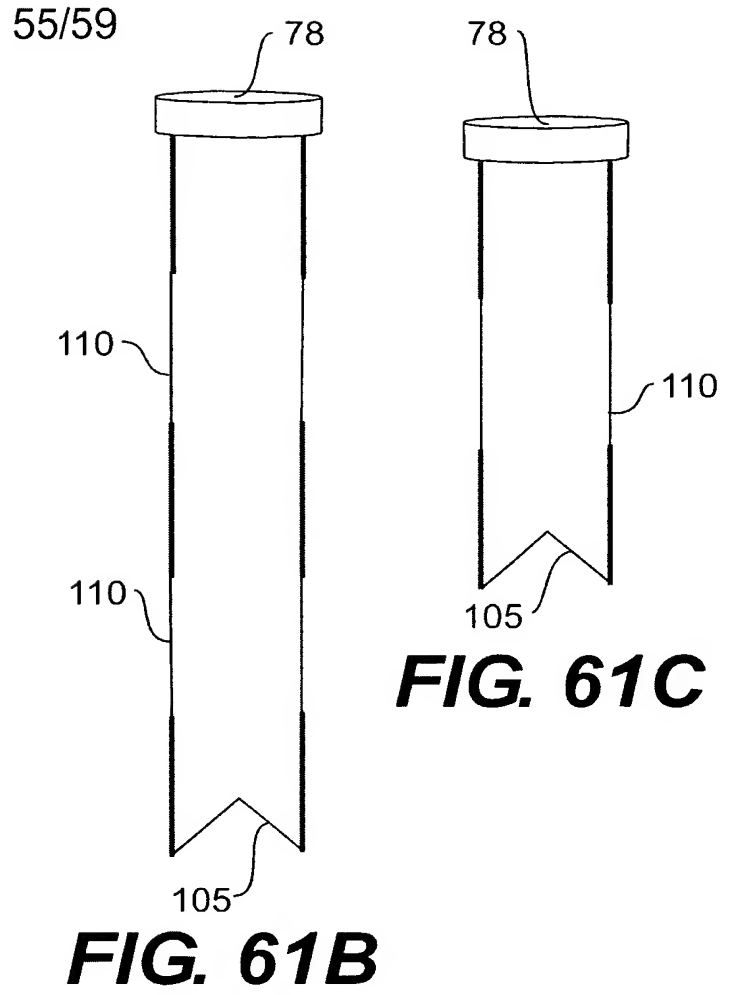
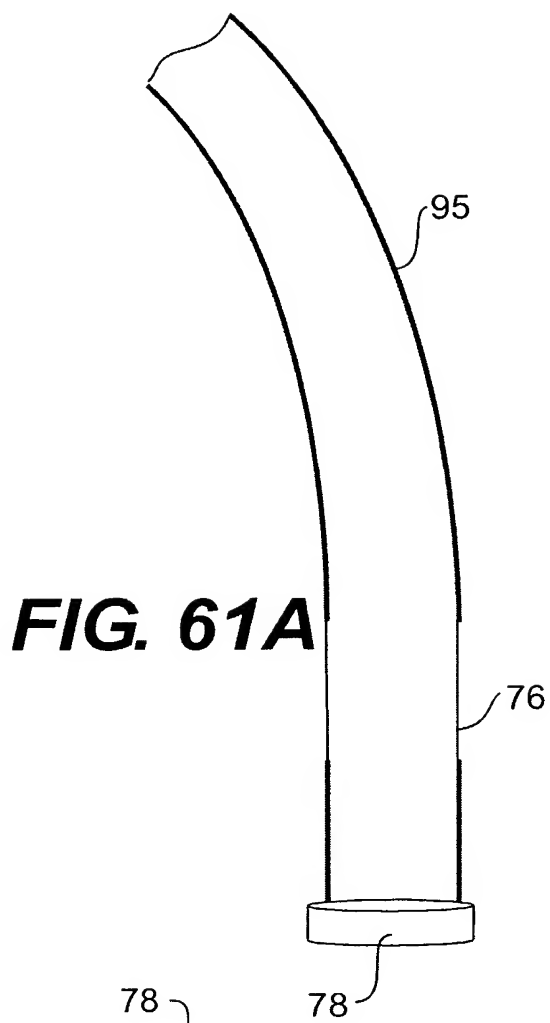


FIG. 60



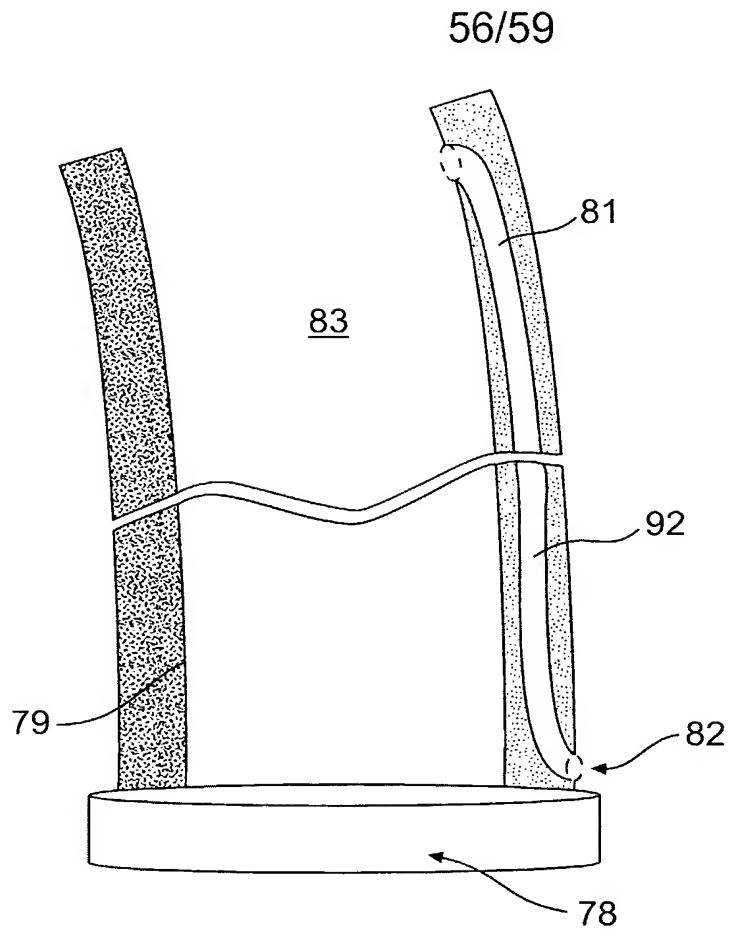


FIG. 62

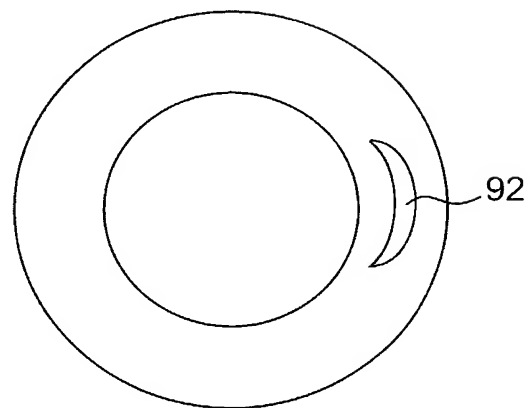
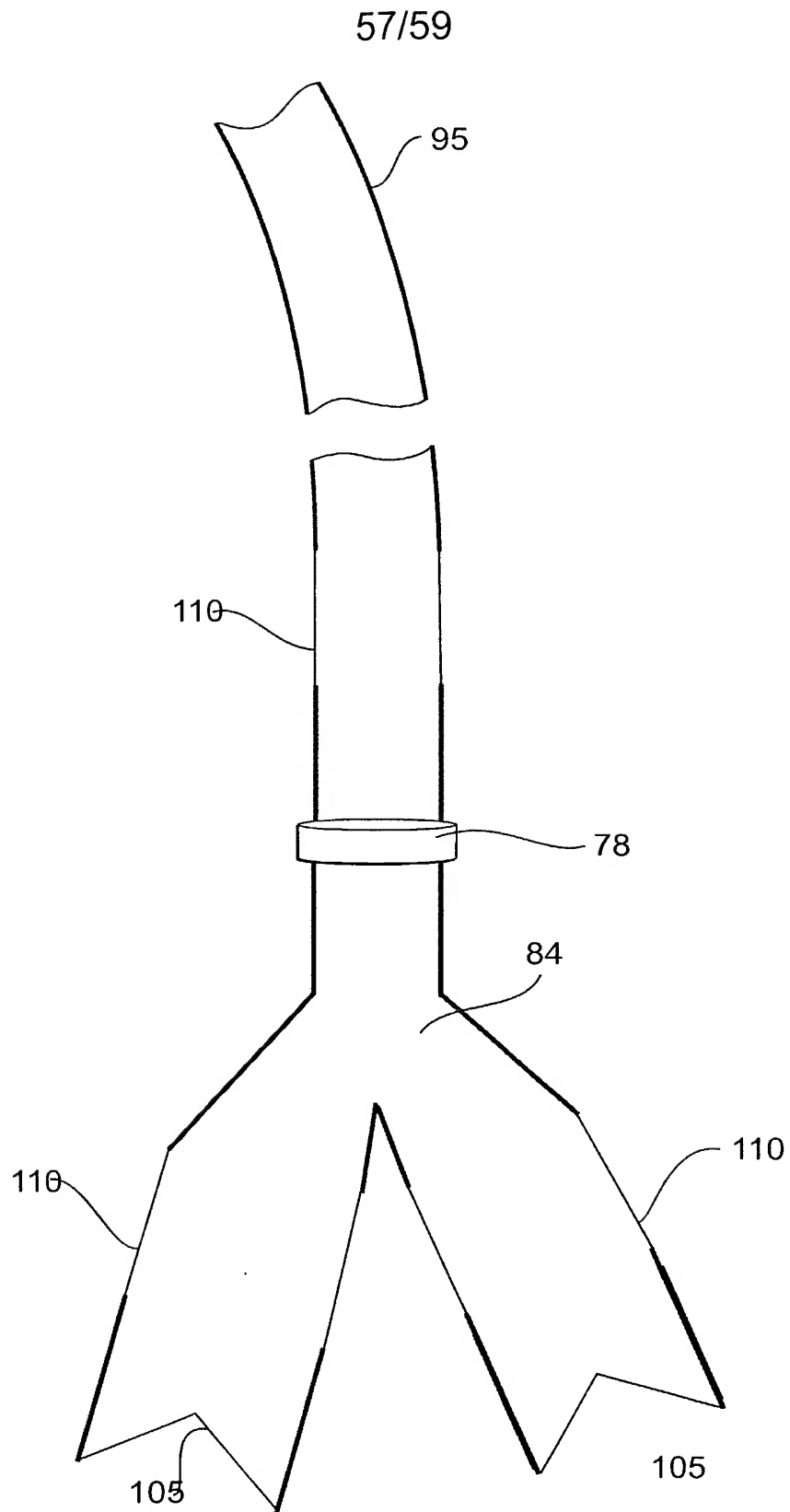


FIG. 63

**FIG. 64**

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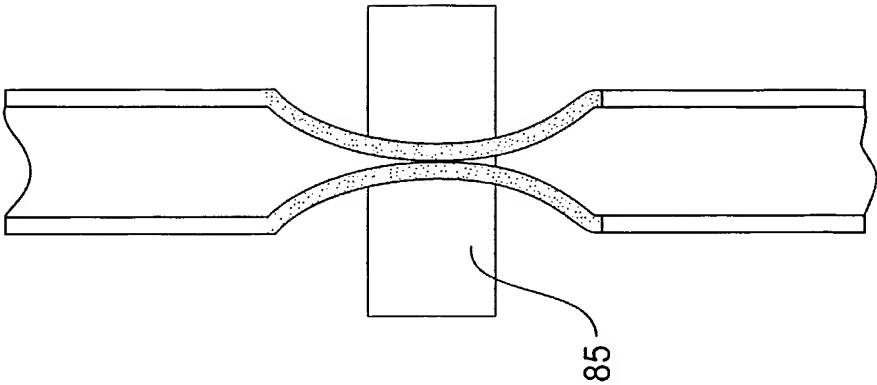


FIG. 65C

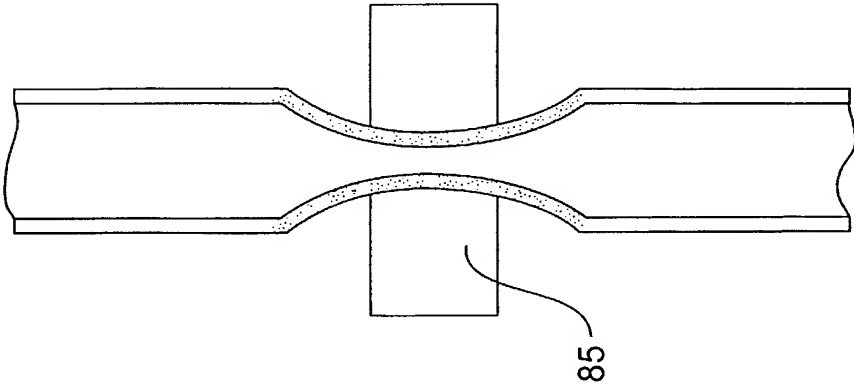


FIG. 65B

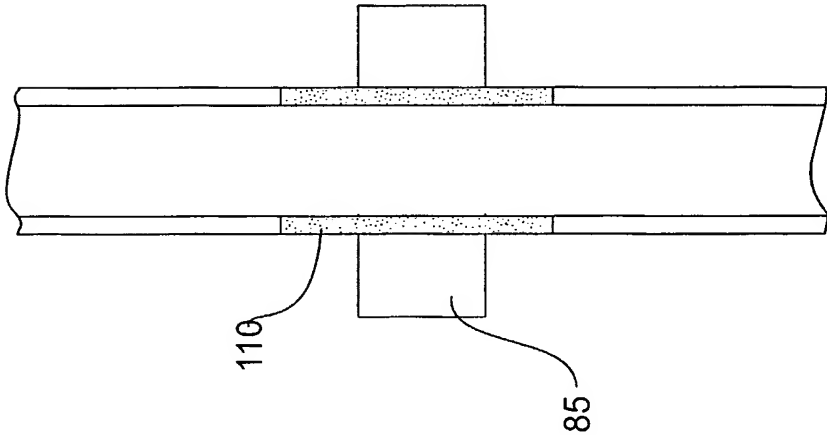


FIG. 65A

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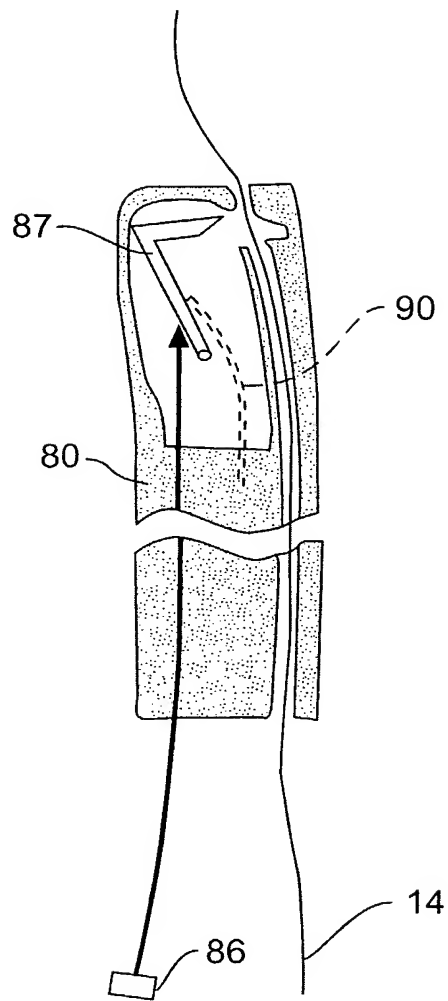


FIG. 66

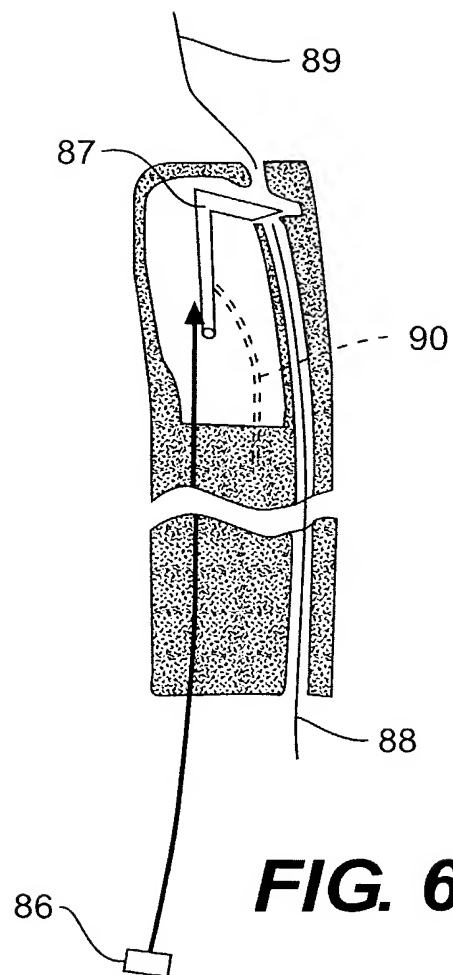


FIG. 67

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US03/08210

A. CLASSIFICATION OF SUBJECT MATTER IPC(7) : A61F 2/06 US CL : 623/1.11 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 623/1.11; 604/191 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X, P --- Y, P	US 6,524,335 B1 (HARTLEY et al) 25 February 2003 (25.02.2003), Figure 3; column 1, Line 65, column 2, Line 63; column 3, lines 1-10 and 45-50 and column 4, line 42-column 6, line 2.	1-3, 6-20, 22-28, 30-34, 36-42, 44-56, 58-60 ----- 1, 5, 21, 29, 35, 43, 57
Y	US 5,911,710 A (BARRY et al) 15 June 1999 (15.06.1999), column 2, lines 15-16; Figure 6; column 2, lines 48-50; and column 5, line 60.	21, 35, 43
Y, P	US 6,511,468 B1 (CRAGG et al) 28 January 2003 (28.01.2003), column 5, lines 44-46; column 7, line 45; column 8, lines 42-53.	4, 5, 29, 57
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
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63110-1003 (US).

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ning of each regular issue of the PCT Gazette.*

(54) Title: CATHETER-BASED FASTENER IMPLANTATION APPARATUS AND METHODS WITH IMPLANTATION
FORCE RESOLUTION

(57) Abstract: Apparatus and methods implant a fastener in a targeted body region, e.g., a hollow body cavity or an intraluminal space. The apparatus and methods deploy in targeted body region a fastener attachment assembly that carries an actuated member. The actuated member is selectively operable to generate an implantation force to implant a fastener into tissue within the targeted body region. The fastener can be implanted, e.g., to secure a prosthesis, e.g., an endovascular graft. The systems and apparatus apply a resolution force at or near the actuated member, thereby making possible a stable and dependable catheter-based fastening platform.



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Patent

**CATHETER-BASED FASTENER IMPLANTATION APPARATUS
AND METHODS WITH IMPLANTATION FORCE RESOLUTION**

Related Applications

This application claims the benefit of co-pending United States Patent Application Serial No. 10/307,226, filed November 29, 2002. This application also claims the benefit of co-pending United States Patent Application Serial No. 10/271,334, filed October 15, 2002. This application also claims the benefit of co-pending United States Patent Application Serial No. 10/099,149, filed March 15, 2002, which is a divisional of United States Patent Application Serial No. 09/787,135, filed September 17, 1999, entitled "Endovascular Fastener Applicator," which claims the benefit of U.S. Provisional Application Serial No. 60/101,050 filed September 18, 1998, and which also claims the benefit of United States Patent Application Serial No. 09/640,554, filed August 18, 2000, entitled "Endovascular Device for Application of Prosthesis with Sutures" (now United States Patent 6,336,933), which is a continuation of United States Patent Application Serial No. 09/266,200, filed March 10, 1999, entitled "Endovascular Device for Application of Prosthesis with Sutures" (now abandoned), and which further claims the benefit of Argentine Patent Application Serial No.

- 2 -

P19980101145, filed March 13, 1998, entitled "Endovascular Device for Application of Prosthesis with Sutures." This application also claims the benefit of co-pending United States Provisional Application Serial No. 60/333,937 filed 28 November 2001.

Field of the Invention

The invention relates generally to the delivery of a prosthesis to a targeted site within the body, e.g., for the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel.

Background of the Invention

The weakening of a vessel wall from damage or disease can lead to vessel dilatation and the formation of an aneurysm. Left untreated, an aneurysm can grow in size and may eventually rupture.

For example, aneurysms of the aorta primarily occur in abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation. Aneurysms can also occur in the thoracic region between the aortic arch and renal arteries. The rupture of an aortic aneurysm results in massive hemorrhaging and has a high rate of mortality.

Open surgical replacement of a diseased or damaged section of vessel can eliminate the risk of vessel rupture. In this procedure, the diseased or damaged section of vessel is removed and a prosthetic graft, made either in a straight or bifurcated configuration, is installed and then permanently attached and sealed to the ends of the native vessel by suture. The prosthetic grafts for these procedures are usually unsupported woven tubes and are typically made from polyester, ePTFE or other suitable materials. The grafts are longitudinally unsupported so they can accommodate changes in the morphology of the aneurysm and native

- 3 -

vessel. However, these procedures require a large surgical incision and have a high rate of morbidity and mortality. In addition, many patients are unsuitable for this type of major surgery due to other co-morbidities.

Endovascular aneurysm repair has been introduced to overcome the problems associated with open surgical repair. The aneurysm is bridged with a vascular prosthesis, which is placed intraluminally. Typically these prosthetic grafts for aortic aneurysms are delivered collapsed on a catheter through the femoral artery. These grafts are usually designed with a fabric material attached to a metallic scaffolding (stent) structure, which expands or is expanded to contact the internal diameter of the vessel. Unlike open surgical aneurysm repair, intraluminally deployed grafts are not sutured to the native vessel, but rely on either barbs extending from the stent, which penetrate into the native vessel during deployment, or the radial expansion force of the stent itself is utilized to hold the graft in position. These graft attachment means do not provide the same level of attachment when compared to suture and can damage the native vessel upon deployment.

Summary of the Invention

One aspect of the invention provides apparatus and methods for implanting a fastener in a targeted body region, e.g., within a hollow body organ or an intraluminal space. The apparatus and methods deploy into the targeted body region a fastener attachment assembly that includes an actuated member. The actuated member is selectively operable to generate an implantation force to implant a fastener into tissue within the targeted body region. The fastener can be implanted, e.g., to secure a prosthesis. The prosthesis can comprise, e.g., an endovascular graft, which can be deployed without damaging the native blood vessel in

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either an arterial or a venous system. The endovascular graft can comprise, e.g., a radially expanding vascular stent and/or a stent-graft. The graft can be placed in the vasculature, e.g., to exclude or bridge an aneurysm, for example, an abdominal aortic aneurysm. The graft desirably adapts to changes in aneurysm morphology and repairs the endovascular aneurysm. The fastening apparatus and methods can be deployed through the vasculature and manipulated from outside the body, to deliver a fastener to attach the graft to the vessel wall.

According to this aspect of the invention, the systems and apparatus apply a resolution force to counteract or oppose some or all or a substantial portion of the implantation force. It is desirable to resolve some or all or a substantial portion of the implantation force within the vessel lumen (or other hollow body organ) itself, and preferably as close to the implantation site as possible, thereby making possible a stable and dependable catheter-based fastening platform.

In one embodiment, the resolution force comprises a substantially equal and opposite counteracting force to a location on the wall of the vessel or hollow body organ, desirably generally opposite to the implantation site.

In one embodiment, the actuated member comprises a driven member for implanting a helical fastener. However, the actuated member can comprise any mechanism for exerting an implantation force using, e.g., ultrasonic, laser, or impact concepts.

In one embodiment, the systems and methods includes a directing component and a fastener applier component. The directing component directs and/or positions the fastener applier component at or near the desired implant location. In this arrangement, the

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directing component can include means to stabilize the position the directing component, thereby providing a resolution force, and/or the directing component can be sized and configured to itself provide a sufficient resolution force with or without additional stabilization means. In another arrangement, the fastener applier component can be sized and configured to itself provide a sufficient resolution force with or without additional stabilization means, and with or without a resolution force contributed by the directing component.

In one embodiment, the stabilization means can include expandable members, membranes, linkages and/or other mechanical systems to stabilize the directing component within the hollow body organ or vessel. The stabilization means can also include means to grasp and/or anchor to the wall of the hollow body organ, vessel or prosthesis prior to implanting a fastener. The grasping or anchoring means can include penetrating needles and/or hooks or barbs.

In one embodiment, the stabilization means can be associated with the fastener applier component instead of or in combination with stabilization means associated with the directing component.

In one embodiment, the stabilization means can take the form of a stabilization device separate from the directing component and applier component. In this arrangement, the separate stabilization device is used in cooperation with the directing component and/or the fastener applier component.

Brief Description of the Drawings

The invention will be understood from the following detailed description of preferred embodiments, taken in conjunction with the accompanying drawings, wherein:

Fig. 1 is a perspective view of one embodiment

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of an endovascular graft delivery device shown positioned within an abdominal aortic aneurysm;

Fig. 2 is a perspective view of one embodiment the deployment of an endovascular graft within the aneurysm of Fig. 1;

Fig. 3 is a perspective view of a fully deployed straight endovascular graft of Fig. 2;

Fig. 4 is a perspective view of a fully deployed bifurcated endovascular graft broken away to show an anchoring scaffold at one end;

Fig. 5 is a perspective view similar to Fig. 5 showing an alternative scaffold structure;

Fig. 6 is a perspective view showing one embodiment of a device for directing the fastener applier;

Fig. 7 is a perspective view showing the device of Fig. 6 upon insertion within the deployed endovascular graft of Fig. 3 with both the graft and scaffolding broken away;

Fig. 8 is a perspective view of the device of Fig. 6 showing activation of one embodiment of a stabilizing device attached to the directing device;

Fig. 9 is a perspective view of the control assembly in Fig. 8 articulating the directing device of Fig. 6;

Fig. 10 is a perspective view of an alternative embodiment of the stabilization device of Fig. 8;

Fig. 11 is a perspective view showing the activation of the alternative stabilization device of Fig. 10;

Fig. 12 is a perspective view showing another embodiment of the stabilization device of Fig. 8;

Fig. 13 is a perspective view showing activation of the stabilization device of Fig. 12;

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Fig. 14 is one embodiment of the fastener applier;

Fig. 14A is an enlarged view of the distal end of the fastener applier shown in Fig. 14, showing the details of the fastener drive mechanism;

Fig. 14B is a section view of the interior of the handle of the fastener applier shown in Fig. 14;

Fig. 15 is a perspective view of the fastener applier of Fig. 14 being positioned within directing device of Fig. 6;

Fig. 16 is an enlarged cross-sectional view of one embodiment of the fastener applier of Fig. 14;

Fig. 17 is an enlarged cross-sectional view of the attachment applier showing one embodiment of the proximal end of the helical fastener and the drive mechanism;

Fig. 18 is a enlarged perspective view of one embodiment of the helical fastener of Fig. 16;

Fig. 19 is an enlarged view of the attachment applier showing one embodiment of the control assembly that activates the fastener applier;

Fig. 20 is an enlarged view of the attachment applied activated with a fastener implanted into the graft and vessel wall;

Fig. 21 is an enlarged view of the completed attachment of the proximal graft of Fig. 3 to the vessel wall with fasteners;

Fig. 22 is a perspective view of the graft of Fig. 4 completely attached to the vessel;

Fig. 23 is an enlarged section view of the drive mechanism of the fastener applier shown in Fig. 14, showing a contact/force sensing assembly that disables the applier in the absence of desired contact between the fastener and a targeted tissue region;

Fig. 24 is an enlarged section view of the

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drive mechanism of the fastener applier shown in Fig. 14, showing the contact/force sensing assembly enabling use of the applier in response to desired contact between the fastener and the targeted tissue region;

Figs. 25A and 25B are enlarged views of the distal end of a fastener applier showing the details of an alternative embodiment of the fastener drive mechanism;

Fig. 26A is an enlarged section view of the drive mechanism of the fastener applier shown in Figs. 25A and 25B showing a contact/force sensing assembly that disables the applier in the absence of desired contact between the fastener and a targeted tissue region;

Figs. 26B and 26C are enlarged section views of the drive mechanism of the fastener applier shown in Figs. 25A and 25B, showing the contact/force sensing assembly enabling use of the applier in response to desired contact between the fastener and the targeted tissue region;

Fig. 27 is a perspective view of a helical fastener that can be used in association with the fastener applier shown in Figs. 14, 23, and 24;

Fig. 28A is a perspective view of a helical fastener that can be used in association with the fastener applier shown in Figs. 25A and 25B;

Fig. 28B is perspective view of a helical fastener that can be used in association with the fastener applier shown in Figs. 26A to 26C;

Fig. 29 is an enlarged side view, partially in section, of a fastener applier having an angled applicator end that can be used to deploy the helical fastener shown in Fig. 27 without use of a separate directing device;

Fig. 30 is an enlarged side view, partially in section, of an alternative embodiment of an angled

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fastener applier that can be used to deploy the helical fastener shown in Fig. 27 without use of a separate directing device;

Fig. 31 is an enlarged side view, partially in section, of an alternative embodiment of an angled fastener applier that can be used to deploy the helical fastener shown in Fig. 27 without use of a separate directing device, the fastener applier having an articulating applicator end;

Fig. 32 is a perspective view of an endovascular prosthesis shown positioned within an abdominal aortic aneurysm, the prosthesis including an integrated fastener assembly;

Fig. 33 is a perspective view of the endovascular prosthesis shown in Fig. 32, with an intraluminal tool deployed to operatively interact with the integrated fastener assembly, to temporarily or permanently anchor the prosthesis to the wall of the vessel;

Fig. 34 is a side view of a fastener that forms a part of the integrated fastener assembly shown in Fig. 33, the fastener having a stem, which is shown in a normally spread-apart condition before its association with the integrated fastener assembly;

Fig. 35 is a side view of the fastener shown in Fig. 34, the fastener stem now being shown in a closed condition and housed within a grommet that forms a part of the integrated fastener assembly;

Figs. 36 and 37 are side views showing the use of the intraluminal tool shown in Fig. 33 to apply force to drive the fastener from its position shown in Fig. 35 and through the vessel wall;

Fig. 38 is the integrated fastener assembly after deployment to anchor a prosthesis to a vessel wall;

Fig. 39 is a side view showing the use of a

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tracking wire to guide a intraluminal tool into contact with a fastener, so that force can be applied to drive the fastener through the vessel wall;

Fig. 40 is an embodiment of a prosthesis delivery catheter for a prostheses in which the stent structure covers only a portion of the prosthesis, the catheter including an array of stabilization struts to help hold the prosthesis in position against the flow of blood;

Fig. 41 is another embodiment of a prosthesis delivery catheter for a prostheses in which the stent structure covers only a portion of the prosthesis, the catheter including an array of inverted stabilization struts to help hold the prosthesis in position against the flow of blood; and

Fig. 42 is another embodiment of a prosthesis delivery catheter for a prostheses in which the stent structure covers only a portion of the prosthesis, the catheter including a stabilization basket to help hold the prosthesis in position against the flow of blood.

Fig. 43 is an elevation view of an alternative stabilization device, comprising tissue gripping elements.

Figs. 44A and 44B are elevation views of a fastener applier that carries an expandable basket-like structure that serves as a stabilization device, Fig. 44A showing the basket-like structure in a generally collapsed condition for intravascular deployment and Fig. 44B showing the basket-like structure in an expanded condition against a vessel wall and graft for deployment of a fastener.

Fig. 45 shows, in diagrammatic fashion, the resolution of an implantation force with a counteracting force within a vessel or hollow body organ.

Detailed Description of the Invention

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I. DELIVERING A PROSTHESIS

Fig. 1 depicts an endovascular graft delivery catheter 10 as it is being positioned over a guidewire 12 in a body lumen. The catheter 10 carries a prosthesis 14 (see Fig. 2), which is placed at a targeted site, e.g., by radial expansion of the prosthesis 14 (see Fig. 3). After partial or complete expansion of the prosthesis 14, one or more fasteners 28 (see Figs. 15 and 16) are introduced by a fastener attachment assembly (as will be described in greater detail later) to anchor the prosthesis 14 in place.

For the purposes of illustration, Fig. 1 shows the targeted site as being within an abdominal aortic aneurysm 11. The targeted site can be elsewhere in the body. In the illustrated arrangement, the prosthesis 14 takes the form of an endovascular graft.

Fig. 2 depicts the initial stage of graft deployment at the targeted site. While the deployment method can vary, in the illustrated embodiment, the delivery catheter 10 has a movable cover 13, which overlays the graft 14. When the cover 13 is pulled proximally, the graft 14 is free to radially expand, thereby enlarging to contact the internal walls of the blood vessel. The graft 14 is shown to be self-expanding. Alternatively, the graft 14 can utilize an expanding member, such as a balloon or mechanical expander.

The process of graft deployment is continued, until the graft 14 is fully deployed or partially deployed within the vessel. The graft 14 can be sized and configured to be either straight or bifurcated form. Fig. 3 depicts a completely deployed straight graft 14. Fig. 4 depicts a completely deployed bifurcated graft 15.

A. The Prosthesis

The graft 14 desirably incorporates a support frame or scaffold 16. The scaffold 16 may be elastic, e.g.,

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comprised of a shape memory alloy elastic stainless steel, or the like. For elastic scaffolds, expanding typically comprises releasing the scaffolding from a constraint to permit the scaffold to self-expand at the implantation site. In the illustrated arrangement, the cover 13 serves as a radial constraint. Alternatively, placement of a tubular catheter, delivery sheath, or the like over the scaffold 16 can serve to maintain the scaffold in a radially reduced configuration. In this arrangement, self-expansion of the scaffold 16 is achieved by pulling back on the radial constraining member, to permit the scaffold 16 to assume its larger diameter configuration.

Alternatively, the scaffold 16 may be constrained in an axially elongated configuration, e.g., by attaching either end of the scaffold to an internal tube, rod, catheter or the like. This maintains the scaffold 16 in the elongated, reduced diameter configuration. The scaffold 16 may then be released from such axial constraint in order to permit self-expansion.

Alternatively, the scaffold 16 may be formed from a malleable material, such as malleable stainless steel of other metals. Expansion may then comprise applying a radially expansive force within the scaffold to cause expansion, e.g., inflating a scaffold delivery catheter within the scaffold in order to affect the expansion. In this arrangement, the positioning and deployment of the endograft can be accomplished by the use of an expansion means either separate or incorporated into the deployment catheter. This will allow the endograft to be positioned within the vessel and partially deployed while checking relative position within the vessel. The expansion can be accomplished either via a balloon or mechanical expansion device. Additionally, this expansion stabilizes the position of the endograft within the artery by resisting

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the force of blood on the endograft until the endograft can be fully deployed.

The graft 14 may have a wide variety of conventional configurations. It can typically comprise a fabric or some other blood semi-impermeable flexible barrier which is supported by the scaffold 16, which can take the form of a stent structure. The stent structure can have any conventional stent configuration, such as zigzag, serpentine, expanding diamond, or combinations thereof. The stent structure may extend the entire length of the graft, and in some instances can be longer than the fabric components of the graft. Alternatively, the stent structure can cover only a small portion of the prosthesis, e.g., being present at the ends. The stent structure may have three or more ends when it is configured to treat bifurcated vascular regions, such as the treatment of abdominal aortic aneurysms, when the stent graft extends into the iliac arteries. In certain instances, the stent structures can be spaced apart along the entire length, or at least a major portion of the entire length, of the stent-graft, where individual stent structures are not connected to each other directly, but rather connected to the fabric or other flexible component of the graft.

One illustrative embodiment of the graft scaffold 16 or stent structure is illustrated in the area broke away in Fig. 4. Here, the stent structure is in the form of a simple zigzag pattern, however it is contemplated that the stent design could involve more complex patterns 17 as depicted in Fig. 5. Although only one stent structure within the graft is depicted, in Fig. 4 and 5, it is contemplated that multiple independent stent structures could be incorporated into the graft, as previously described.

Fig. 40 shows an embodiment of a prosthesis delivery

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catheter 600 for a prostheses 14 in which the stent structure 16 covers only a portion of the prosthesis, e.g., being present only at the ends. As shown in Fig. 40, the prosthesis delivery catheter 600 (which is shown deployed over a guidewire 610) includes an array of stabilization struts 612 that are releasably coupled to the stent structure 16 at the end of the prosthesis 14, e.g., by sutures that can be released by pulling on a drawstring (not shown) that passes through a lumen in the catheter 600. The stabilization struts 612 hold the self-expanding stent structure 16 in position against the vessel wall 34, while the remainder of the prosthesis 14 is being deployed (by withdrawal of a delivery sheath 614). The struts 612 support the stent structure 16 (and thus the overall prosthesis 14) against the force of blood flow through the vessel during prosthesis deployment. The catheter 600 can also include a nose cone 618 at its distal end to diffuse blood flow toward the vessel wall, to aid in supporting the prosthesis 14 during its deployment. Upon deployment of the prosthesis 14, the struts 612 can be detached from the stent structure 14 by pulling upon the drawstring to release the sutures, and the catheter 600 is withdrawn over the guidewire 610 through the delivery sheath 614 (the struts 612, freed from the stent structure 16, fold back upon the catheter 600 during passage through the delivery sheath 614).

Fig. 41 shows an alternative embodiment of a prosthesis delivery catheter 700 for a prostheses 14 in which the stent structure 16 covers only a portion of the prosthesis, e.g., being present at the ends. As shown in Fig. 40, the prosthesis delivery catheter 700 (which is also shown deployed over a guidewire 710) includes an array of inverted stabilization struts 712 that are releasably coupled to the stent structure 16 at the end

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of the prosthesis 14, e.g., by sutures that can be released by pulling on a drawstring (not shown) that passes through a lumen in the catheter 700. The inverted stabilization struts 712, like the struts 612 shown in Fig. 40, hold the self-expanding stent structure 16 in position against the vessel wall 34, while the remainder of the prosthesis 14 is being deployed (by withdrawal of a delivery sheath 714). Like the catheter 600 in Fig. 40, the catheter 700 can also include a nose cone 718 at its distal end to diffuse blood flow toward the vessel wall. Upon deployment of the prosthesis 14, the struts 712 are detached from the stent structure 14 by pulling upon the drawstring (not shown), and the catheter 700 is withdrawn over the guidewire 710 through the delivery sheath 714 (the struts 612, freed from the stent structure 16, fold back upon the catheter 600 during passage through the delivery sheath 614).

Fig. 42 shows another alternative embodiment of a prosthesis delivery catheter 800 for a prostheses 14 in which the stent structure 16 covers only a portion of the prosthesis, e.g., being present at the ends. As shown in Fig. 42, the prosthesis delivery catheter 800 (which is also shown deployed over a guidewire 810) includes a self-expanding stabilization basket 812. The stabilization basket 812 holds the self-expanding stent structure 16 in position against the vessel wall, while the remainder of the prosthesis 14 is being deployed (by withdrawal of a delivery sheath 814). Like the catheters 600 and 700 in Figs. 40 and 41, the catheter 800 can also include a nose cone 818 at its distal end to diffuse blood flow toward the vessel wall. Upon complete deployment of the prosthesis 14, the stabilization basket can be placed into a collapsed condition by withdrawal through the delivery sheath 814, as the catheter 800 is withdrawn over the guidewire 810.

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In all of the just-described embodiments, if the prosthesis 14 has been fully deployed prior to the introduction of the fasteners 28, and/or the prosthesis delivery catheter 600, 700, or 800 has been withdrawn from the targeted site, the guidewire 610, 710, 810 can be subsequently used to deploy a fastener attachment assembly for the prosthesis 14 to the targeted site, as will be described in greater detail next. Alternatively, if the prosthesis 14 has not been fully deployed at the time the fasteners 28 are applied -- or if, for whatever reason, withdrawal of the prosthesis delivery catheter 600, 700, or 800 is not desired -- the prosthesis delivery catheter 600, 700, or 800, and its respective guidewire 610, 710, or 810, can be retained at the targeted site, while a fastener attachment assembly for the prosthesis 14 is introduced into the targeted site over a separate guidewire from another body access point. In this arrangement, deployment of the prosthesis 14 and/or withdrawal of the prosthesis delivery catheter 600, 700, or 800 can be completed after the fasteners 28 have been applied.

II. FASTENING THE PROSTHESIS

In a desired embodiment, a fastener attachment assembly is provided that makes possible intraluminal fastener attachment. The attachment assembly can be variously constructed.

A. Two Component Fastener Guide and Attachment Assembly

In one arrangement, the fastener attachment assembly comprises a fastener guide or directing component 18 and a fastener applier component 27. The guide component 18 desirably has a steerable or deflectable distal tip, which is initially deployed over the guidewire 12. In use in the illustrated embodiment, the guidewire 12 that is used to deliver and position the prosthesis 14 remains

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within the vessel for subsequent deployment of the fastener guide component 18. Alternatively, another guidewire from a different body access point can be used for deployment of the fastener guide component 18. In either arrangement, the fastener applier component 27 is desirably deployed through the guide component 18 after removal of the guidewire over which the guide component 18 has been delivered. The fastener applier 27 carries at least one fastener 28 and a fastener drive mechanism 100 for advancing the fastener 28, so that it penetrates the prosthesis 14 and underlying vessel wall, to thereby anchor the prosthesis 14 firmly in place.

1. Fastener Directing Component

Fig. 6 depicts one embodiment of the directing or guide component 18 that forms a part of the fastener attachment assembly. The component 18 includes an interior lumen that accommodates passage of an obturator 19. The obturator 19 has a lumen to allow for delivery of the directing component 18 over the guidewire 12, as shown in Fig. 7. Once deployed in a desired location, the obturator 19 and guidewire 12 are removed, leaving the central lumen open for passage of the fastener applier component 27, as will be described later.

In the illustrated embodiment (see Fig. 8), the directing component 18 includes a control assembly 21. In one embodiment the control assembly 21 features a movable wheel or lever 22, which operate interior steering wires in a conventional fashion to deflect the distal tip 23 of the directing component 18 toward a desired location, as seen in Fig. 9. It is contemplated that the control assembly 21 for the directing component 18 could be activated mechanically, electrically, hydraulically or pneumatically. The control assembly 21 has a through lumen to allow for the passage of the obturator 19 (as just described) and the fastener applier component 27, as

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will be described next.

2. Fastener Applier Component

Fig. 14 shows one embodiment of the fastener applier component 27 that forms a part of the fastener attachment assembly. As Fig. 15 depicts, the fastener applier component 27 is deployed through the central lumen of the directing component 18 to the site where a fastener 28 will be installed.

Located at the distal end of the fastener applier component 27 (see Fig. 14) is a fastener drive mechanism 100. In the illustrated embodiment (see Fig. 14A), the drive mechanism 100 includes a driver 29 that is coupled to a carrier 102. The coupling between the driver 29 and carrier 102 can take different forms - e.g., magnets, graspers, or other suitable mechanical connection. In the embodiment illustrated in Fig. 14A, the driver 29 and carrier 102 are integrally connected as a single unit.

The carrier 102 is sized and configured to engage a selected fastener 28. In Fig. 14A, the fastener takes the form of a helical fastener of the type shown in Figs. 18 and 27. As best shown in Fig. 27, and as will be described in greater detail later, the helical fastener 28 in Fig. 26 is an open coil 148 with a sharpened leading tip 142. The proximal end 144 of the fastener 28 includes an L-shaped leg 146. The L-shaped leg 146 desirably bisects the entire interior diameter of the coil 148; that is, the L-shaped leg 146 extends completely across the interior diameter of the coil 148, as Fig. 27 shows. The L-shaped leg 146 serves to engage the carrier 102 of the fastener applier 27, which rotates the helical fastener to achieve implantation. The L-shaped leg 146 also serves as a stop to prevent the helical fastener from penetrating too far into the tissue.

The carrier 102 in Fig. 14A includes a slot 180,

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which receives the L-shaped leg 146 to couple the fastener 28 for rotation with the carrier 102. The turns of the coil 148 rest in complementary internal grooves 32 that surround the carrier 102. The grooves 32 could be positioned along the entire length of the fastener 28 or within a portion of its length.

The actuation of the drive mechanism 100 can, of course, be accomplished in various ways, e.g., mechanical (i.e., manual or hand-powered), electrical, hydraulic, or pneumatic. In the illustrated embodiment (see Fig. 14B), a drive cable 30 couples the fastener driver 29 to an electric motor 106 carried in the applicator handle 108. The drive cable 30 is desirably made of a suitable material that allows for both bending and rotation. Driven by the motor 106 (which is, in turn, under the control of motor control unit 31, as will be described later), the drive cable 30 rotates the driver 29 and, with it, the carrier 102. The carrier 102 imparts rotation and torque to the helical fastener 28 for implantation in tissue.

Fig. 16 is an enlarged cross-sectional view of fastener applicator 27 and directing device 18. Fig. 17 is an enlarged cross-sectional view of the fastener applicator 27 with a cross-section of the fastener driver 29 depicting the engagement between the fastener driver 29 and helical fastener 28. Fig. 19 depicts the fastener applicator 27 during activation of the fastener drive mechanism 100. Activation of the drive mechanism 100 rotates, as a unit, the drive shaft 30, the driver 29, the carrier 102, and helical fastener 28. This rotation causes the helical fastener 28 to travel within the internal grooves 32 of the fastener applicator and into the prosthesis 14 and vessel wall 34 (see Fig. 20). Fig. 21 illustrates a completed helical fastener 28 attachment of the graft 14 to the vessel wall 34.

In use, the applicator component 27 is advanced through

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the directing component 18 and into contact with the prosthesis. The operator actuates the control unit 31 by contacting a control switch 110 (see Figs. 14 and 14B). This action causes the helical fastener 28 to be rotated off the carrier 102 and through the prosthesis 14 and into the vessel wall 34. The motor control unit 31 desirably rotates the drive cable 30 a specific number of revolutions with each activation command. This can be accomplished by incorporating a mechanical or electrical counter.

With the deployment of a fastener 28, the fastener applier component 27 is retrieved through the directing component 18, and another fastener 28 is loaded into the carrier 102. The directing component 18 is repositioned, and the applier component 27 is advanced again through the directing component 18 and into contact with the prosthesis 14. The operator again actuates the control unit 31 by contacting the control switch 110 to deploy another fastener 28. This process is repeated at both proximal and/or distal ends of the prosthesis 14 until the prosthesis 14 is suitably attached and sealed to the vessel wall 34. It is contemplated that from about two to about twelve fasteners 28 may be applied at each end of the prosthesis 14 to affect anchorage. The fasteners 28 can be applied in a single circumferentially space-apart row, or may be applied in more than one row with individual fasteners being axially aligned or circumferentially staggered.

Fig. 22 illustrates a perspective view of a graft prosthesis attached to the vessel wall both proximally and distally. It is contemplated that the present invention can be used for graft attachment of both straight and bifurcated grafts within the aorta and other branch vessels.

An alternative embodiment of the drive mechanism 100

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is shown in Figs. 25A and 25B. In this embodiment, the driver 29 is coupled to a carrier 150, which forms a part of the helical fastener 28 itself, as also shown in Fig. 28A. As shown in Fig. 28A, the helical fastener 28 is, like the fastener shown in Fig. 27, an open coil 148 with a sharpened leading tip 142. The proximal end 144 of the fastener 28 includes the carrier 150.

The carrier 150 includes a slot 182. The slot 182 engages a drive flange 184 on the driver 29 (see Fig. 25A) to impart rotation of the driver 29 to rotation of the helical fastener 28 during the implantation process. Like the L-shaped leg of the fastener shown in Fig. 27, the carrier 150 also serves as a stop to prevent the helical fastener from penetrating too far into the tissue.

The coupling engagement between the carrier 150 and the driver 29 could be accomplished in various ways, e.g., by separate graspers or grippers, a magnetic couple, or any other suitable mechanical connecting means. In the illustrated embodiment, the driver 29 is made of a magnetized material, and the carrier 150 is made from a material that is magnetically attracted toward the magnetized material. Of course, a reverse arrangement of magnetized and magnetically attracted materials could be used.

In this arrangement, the motor coupling 132 between the drive cable 30 and the motor 106 accommodates axial displacement of the motor cable 30 (left and right in Figs. 25A and 25B) without interrupting the drive connection with the motor 106. With the distal tip of the applier device 27 in contact with the prosthesis 14 (see Fig. 25A), the operator actuates the control unit 31 by contacting a control switch 110. The control unit 31 commands the motor 106 to rotate the drive cable 30 to impart rotation to the driver 29 and the magnetically

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attached helical fastener 28. This action causes the magnetically attached helical fastener 28 to be rotated into prosthesis 14 and the vessel wall 34 (see Fig. 25B). Due to the magnetic coupling, as the fastener 28 is deployed to the left in Fig. 25B, the driver 29 moves in tandem with carrier 150 (also to the left in Fig. 25B). Due to the magnetic coupling between the carrier 150 and the driver 29, the operator must exert a deliberate separation force to decouple the carrier 150 (and, with it, the fastener 28) from the driver 29. This arrangement prevents inadvertent release of a fastener 28.

As before described, with the deployment of a fastener 28, the applier component 27 is retrieved through the directing device 18, and another fastener 28 is magnetically coupled to the driver 29. The directing component 18 is repositioned, and the applier component 27 is advanced again through the directing component 18 and into contact with the prosthesis 14. The operator again actuates the control unit 31 by contacting a control switch 110 to deploy another fastener 28. This process is repeated at both proximal and/or distal ends of the prosthesis 14 until the prosthesis 14 is suitably attached and sealed to the vessel wall 34.

As indicated in the above description, the outer diameter of the applier component 27 is desirably sized and configured to pass through the lumen of the directing component 18, which can take the form of a suitable steerable guide catheter, to direct the applier component 27 to the desired location. As also above described, the applier component 27 is desirably configured to implant one fastener 28 at a time (a so-called "single fire" approach). This is believed desirable, because it reduces the complexity of the design and accommodates access of the applier component 27 through tortuous anatomy. A fastener applier component 27 which carries a single

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fastener can have a lower profile and may be more effective and less traumatic than fastener appliers which carry multiple fasteners. Still, in alternative embodiments, the applier component 27 may, if desired, be configured to carry multiple fasteners. Moreover, the fastener applier 27 may simultaneously deploy multiple fasteners in the preferred circumferentially spaced-apart space pattern described above.

3. Force Resolution

Penetration and implantation of the fastener 28 into tissue using the applier component 27 requires the applier component 27 to exert an implantation force at or near the prosthesis 14 and vessel wall 34. In the illustrated embodiment, the applier component 27 comprises a driven member for implanting a helical fastener. However, the applier component 27 can comprise virtually any actuated member for exerting an implantation force using, e.g., ultrasonic, laser, or impact concepts.

Regardless of the particular way that the implantation force is generated, the implantation force of the applier component 27 is desirably resolved in some manner to provide positional stability and resist unintended movement of the applier component 27 relative to the implantation site. Stated differently, a resolution force is desirably applied to counteract and/or oppose the implantation force of the applier component 27. It is desirable to resolve some or all or a substantial portion of the implantation force within the vessel lumen (or other hollow body organ) itself, and preferably as close to the implantation site as possible.

The tubular body of the directing component 18 and/or the shaft of the fastener applier component 27 can be sized and configured to possess sufficient column strength to resolve some or all or at least a portion of

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the implantation force within the vessel lumen or hollow body organ. In addition, or alternatively, the directing component 18 and/or the fastener applier component 27 can include stabilization means 20 for applying a counteracting force at or near the driven member of the fastener applier component 27 that implants the fastener.

The illustrated embodiments show various alternative embodiments for the stabilization means 20. As shown in Figs. 8 and 9, the stabilization means 20 takes the form of a spring-loaded arm on the directing component 18 for contacting tissue. In this arrangement, the spring-loaded stabilizing means 20 is positioned for deployment when the obturator 19 and guidewire 12 are removed from the directing component 18 (see Fig. 8). In the alternative embodiment shown in Figs. 10 and 11, the stabilization means 20 takes the form of a movable strut assembly 24 on the directing component 18, which contacts tissue. In this alternative arrangement, the movable strut assembly 24 can be activated, e.g., through a lever 25 on the control assembly (see Fig. 11). In both embodiments (Fig. 7 and 10) the stabilizing device 20 is distal to the end of the directing component 18. In the alternative embodiment shown in Fig. 12, the stabilization means 20 takes the form of an expandable member 26 positioned adjacent the distal tip of the directing component 18. In this alternative arrangement (see Fig. 13), the expandable member 26 can be activated, e.g., through a lever 25 on the control assembly 21. However it is also contemplated that this type of stabilizing means 20 could also be inflatable. In another alternative embodiment (see Fig. 43), the stabilization means 20 includes means 200 carried by the directing component 18 and/or the fastener applier component 27 for grasping and/or anchor to the wall of the hollow body organ, vessel or prosthesis prior to implanting a fastener. The grasping

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or anchoring means 200 can include penetrating needles and/or hooks or barbs that are deployed by a control assembly or the like prior to implantation of a fastener.

In all embodiments the stabilizing means 20 could be use to stabilize the directing component 18 either concentrically or eccentrically within the vessel.

Of course, any of these alternative forms of the stabilization means 20 can be associated with the fastener applier 27 in the same fashion they are shown to be associated with the directing component 18, or take some other form of a stabilization mechanism having the equivalent function. In yet another embodiment, the stabilization means 20 can take the form of a separate stabilization device used in cooperation with the directing component 18 and/or the fastener applier component 27. In this arrangement, the separate stabilization device could incorporate any of the alternative forms of the stabilizing devices described above, or some other form of stabilization mechanism.

For example (see Figs. 44A and 44B), the fastener applier 27 can carry about its distal end an expandable basket 202 or basket-like structure. The basket structure 202 surrounds the fastener drive mechanism 100, which has been previously described. The basket structure 202 is operable between a low profile, generally collapsed condition (shown in Fig. 44A) and an expanded profile condition (shown in Fig. 44B) about the fastener drive mechanism 100.

In the generally collapsed condition, the fastener applier 27 can be deployed through a vessel into proximity to a graft 14. Fig. 44A shows the graft 14 to include a self-expanding scaffold 16. When in the generally collapsed condition, the fastener applier 27 can be deployed in its low profile state through the vasculature to the targeted graft site either by itself,

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or through an associated directing component 18 or suitable guide sheath, which can steerable or non-steerable.

When situated at the graft site (see Fig. 44B), the basket structure 202 can be expanded (e.g., by a suitable push-pull control mechanism) into contact with the graft 14. The fastener applier 27 can be maneuvered within the expanded basket structure 202 into contact with the graft 14 and operated to deploy a fastener 28, as previously described. The basket structure 202 serves to resolve at least some of the implantation force to provide positional stability and resist unintended movement of the fastener applier 27.

In all these alternative embodiments, the stabilization means 20 functions to apply a substantially equal and opposite counteracting resolution force within a vessel (see Fig. 45) to a location on the vessel wall, desirably generally opposite to the implantation site. As also just described, the column strength of the associated directing component 18 and/or fastener applier 27 can also serve in conjunction with the stabilization means 20 to resolve the intraluminal implantation force at the implantation site.

The force resolving function that the guiding component 18 and/or the fastener applier component 27 provide serves to counteract or oppose or otherwise resolve the tissue penetration and implantation force of the applier component 27. The force resolving function thereby also resists movement of the applier component 27 relative to the implantation site, thereby making possible a stable and dependable intraluminal (or intra organ) fastening platform.

4. Prosthesis/Tissue Contact Sensing

The fastener applier component 27 desirably incorporates a function that prevents actuation of the

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motor 106 until the tip of the applier component 27 is in a desired degree of contact with the prosthesis or tissue surface. This prevents inadvertent discharge of a fastener 28 and/or separation of the fastener 28. This function can be implemented, e.g., using a contact or force sensor, which is either mechanical or electrical in design.

When the fastener applier component 27 is of the type shown in Figs. 14A, 14B, and 14C (see Figs. 23 and 24), the contact or force sensing function can, e.g., utilize the distal tip 120 of the carrier 102 to transmit a contact force. This force can be transmitted to a force or contact sensing switch 122 located, e.g., within the fastener applier handle 108. In this arrangement, the switch 122 can be part of the electrical circuit between the actuator switch 110 and the control unit 31.

In the illustrated embodiment, the switch 122 includes a stationary switch element 128 (coupled to the interior of the handle 108) and a movable switch element 130 (carried by the drive cable 31). In this arrangement, the motor coupling 132 between the drive cable 30 and the motor 106 accommodates axial displacement of the motor cable 30 (left and right in Figs. 23 and 24) without interrupting the drive connection with the motor 106. The drive cable 30 is coupled by a bearing 134 to the movable switch element 130, so that the switch element 130 moves in response to movement of the drive cable 30. The stationary switch element 128 is not coupled to the movable drive cable 30, which slidably passes through the switch element 130.

Due to this arrangement, axial displacement of the drive cable 30 moves the switch element 130 relative to the switch element 128. More particularly, displacement of the drive cable 30 to the left in Fig. 23 moves the

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switch element 130 to the left, away from the switch element 128. Conversely, displacement of the drive cable 30 to the right in Fig. 23 moves the switch element 130 to the right, toward the switch element 128.

A spring 126 normally biases the switch elements 128 and 130 apart, comprising an electrically opened condition. In this condition, operation of the actuating switch 110 does not serve to actuate the control unit 31, as the electrically open switch 122 interrupts conveyance of the actuation signal to the motor control unit 31. When the switch elements 128 and 130 are in the electrically opened condition, the drive cable 30 is displaced to the left to position the carrier tip 120 beyond the distal tip 124 of the fastener applier 27. The carrier tip 120 therefore makes contact with the prosthesis 14 or tissue in advance of the applier tip 124.

When the carrier tip 120 contacts the surface of the prosthesis or tissue with sufficient force to compress the spring 126, the drive cable 30 is displaced against the biasing force of the spring to the right in Fig. 23.

This moves the switch element 130 to the right. Ultimately, contact between the switch elements 128 and 130 will occur, as shown in Fig. 24. The contact establishes an electrically closed condition. In this condition, operation of the actuating switch 110 serves to actuate the control unit 31. As shown in Figs. 23 and 24, a contact screw 136 can be provided to adjust the amount of displacement required to close the switch elements 128 and 130.

Upon removal of contact force, or in the absence of sufficient contact force, the spring 126 urges the switch elements 128 and 130 toward the electrically opened condition. The distal tip of the carrier 102 is located distally beyond the distal tip of the applier 27.

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It should be appreciated that the translation of movement of the carrier tip 120 to the switch 122 need not occur along the entire length of the drive cable 30. For example, the switch 122 can be located in a translation space between the carrier 102 and the driver 29. In this arrangement, the driver 29, coupled to the drive cable 30 need not accommodate axial displacement. Instead, relative movement of the carrier 102 toward the driver 29 in response to contact with the prosthesis 14 will mechanically couple the carrier 10 with the driver 29 (e.g., through a slot and flange connection similar to that shown in Figs. 25A and 25B), while also closing the switch 122 to energize the circuit between the actuator switch 110 and the motor control unit 31.

When the fastener applier component 27 is of the type shown in Fig. 25A and 25B (see Figs. 26A, 26B, and 26C), the contact or force sensing function can, e.g., utilize a force sensing rod 190 that slidably passes through a central passage 192 in the carrier 150' (the carrier 150' is shown in Fig. 28B), the driver 29 and the drive cable 30. The rod 190 is coupled to the movable switch element 130. In this embodiment, the switch element 130 translates left and right over the drive cable 30, which rotates on a bearing 134 within the switch element 130.

As in the preceding embodiment, the spring 126 normally biases the switch elements 128 and 130 apart, comprising an electrically opened condition. When the switch elements 128 and 130 are in the electrically opened condition, the force sensing rod 190 is displaced to the left beyond the distal tip 124 of the fastener applier component 27. The force sensing rod 190 therefore makes contact with the prosthesis 14 or scaffold structure 16 in advance of the applier tip 124.

When the rod 190 contacts the surface of the

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prosthesis or scaffold structure with sufficient force to compress the spring 126, the rod 190 is displaced against the biasing force of the spring 126 to the right in Fig. 26A. This moves the switch element 130 to the right. Ultimately, contact between the switch elements 128 and 130 will occur, as shown in Fig. 26B. The contact establishes an electrically closed condition. In this condition, operation of the actuating switch 110 serves to actuate the control unit 31. This action causes the helical fastener 28 to be rotated into the scaffold structure 16 and into the vessel wall 34 (see Fig. 26C). Due to the magnetic coupling between the driver 29 and carrier 150', the driver 29 is moved in tandem with attached carrier 150' to the left in Fig. 26B, as the fastener 28 is deployed. Also, due to the magnetic coupling between the carrier 150 and the driver 29, the operator must exert a separation force to decouple the carrier 150 (and, with it, the fastener 28) from the driver 29. As before described, this arrangement prevents inadvertent release of a fastener 28. A contact screw 136 can be provided to adjust the amount of displacement required to close the switch elements 128 and 130.

Upon removal of contact force, or in the absence of sufficient contact force, the spring 126 urges the switch elements 128 and 130 toward the electrically opened condition, moving the tip of the rod 190 out beyond the distal tip 124 of the applier 27.

The contact or force sensing arrangements just described can also generate an audible and/or visual output to the operator, to indicate that sufficient contact force between the applier device 27 and the prosthesis or tissue exists.

B. Angled Component Fastener Guide and Attachment Assembly

In another arrangement (see Fig. 29), the fastener

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attachment assembly comprises a unitary, angled fastener guide and applier component 160. In this arrangement, the component 160 includes a fastener drive mechanism 162 that places the carrier 164 holding the fastener 28 in a perpendicular or near perpendicular position with respect to the prosthesis or tissue. This configuration eliminates the need for a separate steerable guide component 18 for the fastener component 27, previously described.

The drive mechanism 162 can vary. In the illustrated embodiment (shown in Fig. 29), the mechanism 162 includes a beveled drive gear 168 coupled to the drive cable 30. The drive gear 168 operatively meshes with a transfer or pinion gear 170, which is coupled to the carrier 164. The axes of rotation of the drive gear 168 and pinion gear 170 are offset about ninety degrees, so that rotation of the drive cable 30 along the axis of the vessel is translated into rotation of the carrier 164 generally perpendicular to the wall of the vessel. The fastener guide and applier component 160 can be positioned and stabilized within the vessel in various ways, e.g., through the use external spring loaded strut or the like (as shown in association with the directing component 18 discussed above), or by use of an expandable member 166 (as Fig. 29 shows). The expansion member 166 can comprise either a balloon or mechanical expansion device. The expansion member 166 stabilizes the position of both the prosthesis and the fastener guide and applier component 160 within the vessel by resisting the force of blood until the prosthesis can be anchored.

As Fig. 30 shows, the fastener guide and applier component 160 can, if desired, provide an angled deployment between the drive cable 30 and carrier 164 that is somewhat less than ninety-degrees, to aid in intraluminal manipulation of the carrier into

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perpendicular contact position against the wall of the vessel. As Fig. 31 shows, the fastener guide and applicator component 160 can, if desired, be articulated between the drive cable 30 and carrier 164. In this arrangement, a remote control mechanism is desirable provided to move the carrier 164 from a first, generally straight position (shown in phantom lines in Fig. 31) for deployment to the targeted site, to a second, articulated position (shown in solid lines in Fig. 31) for alignment of the carrier 164 in contact against the vessel wall.

III. THE FASTENERS

As illustrated and described thus far, introduction of the fasteners 28 will typically be affected after the prosthesis 14 has been initially placed. That is, initial placement of the prosthesis 14 will be achieved by self-expansion or balloon expansion, after which the prosthesis 14 is secured or anchored in place by the introduction of a plurality of individual fasteners. The fasteners 28 may be placed only through the fabric of the prosthesis 14, i.e., avoiding the scaffold structure. Alternately, the fasteners 28 can be introduced into and through portions of the scaffold structure itself. The prosthesis 14 may include preformed receptacles, apertures, or grommets, which are specially configured to receive the fasteners. The fasteners 28 may be introduced both through the fabric and through the scaffold structure. The fasteners can be introduced singly, i.e., one at a time, in a circumferentially spaced-apart pattern over an interior wall of the prosthesis 14.

In the exemplary embodiment, the fasteners 28 are helical fasteners, so that they can be rotated and "screwed into" the prosthesis 14 and vessel wall. A desired configuration for the helical fastener 28 (see Figs. 27, 28A, and 28B) is an open coil 148, much like a coil spring. This configuration allows the fastener 28 to

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capture a large area of tissue, which results in significantly greater holding force than conventional staples, without applying tissue compression, which can lead to tissue necrosis.

As Figs. 27, 28A, and 28B show, the leading tip 142 of the helical fastener 28 is desirable sharp to allow it to penetrate through the artery wall and/or calcified tissue. This distal tip 142 can be sharpened to cut a helical path through the tissue or it can be sharpened to a point to penetrate the tissue without cutting.

The proximal end 144 of the fastener serves two design functions. The first function is to engage the carrier 102 of the fastener applier 27, which rotates the helical fastener during the implantation process. The second function is to act as a stop to prevent the helical fastener from penetrating too far into the tissue.

In one embodiment (see Fig. 27), the proximal end 144 of the helical fastener 28 includes an L-shaped leg 146 of the coil 148 bisecting the fastener diameter. The leg 146 of the coil 148 comes completely across the diameter to prevent the fastener from being an open coil and to control the depth of penetration into the tissue. In addition, the leg 146 of the coil 148 can be attached to a previous coil to strengthen the entire structure and provide a more stable drive attachment point for the fastener applier. This attachment could be achieved via welding, adhesive or any other suitable means.

Alternatively (as shown in Figs. 28A and 28B), the proximal end 144 of the fastener 28 could incorporate a separate cap or carrier 150 or 150' that serves the same function as the leg 146 of the coil 148 in Fig. 27. The carrier 150 or 150' could feature several methods to attach to the fastener applier drive mechanism 100. These include separate graspers or grippers, a magnetic couple

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(as previously described), or any other suitable mechanical connecting means. In Figs. 28A and 28B, the carrier 150 and 150' includes a slot 180 and 182' to mate with a drive flange (as previously described). As also previously described, a magnetic coupling is implemented between the carrier 150 and 150' and the corresponding drive member, to prevent inadvertent separation during use.

In Fig. 28B, the carrier 150' also includes a passage 152 for holding the contact/force sensing rod 190 shown in Figs. 26A, 26B, and 26C.

The fasteners 28 shown in Figs. 27, 28A, and 28B can be made from stainless steel or other types of implantable metal, however it is also envisioned that the fasteners in the above descriptions could be made from implantable polymers or from a biodegradable polymer or combinations of all materials thereof. Desirably, a fastener 28 will have between 2 and 10 turns and will be between 1 mm and 10 mm long. The space between the individual coils will be between .25 mm and 3 mm. The diameter of the fastener 28 will be between 1 mm and 6 mm.

IV. PROSTHESIS WITH INTEGRATED FASTENER ASSEMBLY

Fig. 32 shows a prosthesis 500 that includes at least one integrated fastener assembly 502. Fig. 32 shows the prosthesis 500 deployed in a targeted intraluminal region, in particular, within an abdominal aortic aneurysm 504. The prosthesis 500 can be deployed elsewhere in the body.

The prosthesis 500 desirably includes a fabric material or the like carried by a support frame or scaffold 504, as previously described. The scaffold 504 can be made, e.g., from an elastic material that self-expands radially during deployment from a sheath, or from a malleable material that expands radially in response to

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a radially expansive force applied within the scaffold by a balloon or a mechanical expansion device.

Following deployment of the prosthesis 500 in the targeted region, the integrated fastener assembly 502 on the prosthesis 500 is manipulated to anchor the prosthesis 500 to the vessel wall. In the illustrated embodiment, the prosthesis 500 carries two integrated fastener assemblies 502, one in each end region of the prosthesis 500.

In the illustrated embodiment, each fastener assembly 502 is imbedded in a reinforced flange area 506 in the respective end region. Each fastener assembly 502 comprises an array of fasteners 508 circumferentially spaced about the flange 506. The number of fasteners 508 in the array can vary, e.g., from about two to about twelve fasteners on each flange area 506. The configuration of the array can also vary, e.g., in the circumferential array, the fasteners 508 can be axially spaced apart as well.

The fasteners 508 can be formed of a metal or plastic material and can be variously constructed. In the illustrated embodiment, each fastener 508 includes a disc-shaped head 512 and a stem 514 that is bifurcated into two wings 516 and 518, which are joined by a plastic or memory material hinge region 520. The material of the hinge region 520 is formed with a resilient memory that biases the wings 516 and 518 to a spread-apart condition (as Fig. 34 shows).

Each fastener 508 is carried within a grommet 510 on the flange area 506 (see Fig. 35). When the hinge region 520 is confined within the grommet 510 (as Fig. 35 shows), the wings 516 and 518 are retained against the resilient memory in an adjacent, closed condition. In response to the application of a pushing or punching force on the head 512 (see Fig. 35), the wings 516 and

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518 are advanced in the closed condition out of the grommet 510, and into and through the adjacent vessel wall (see Fig. 36). Upon continued advancement, the hinge region 520 is freed from the confines of the grommet 510 (see Fig. 37). As a result, the wings 516 and 518 resiliently spring into their normal spread-apart condition.

In this arrangement, an intraluminal tool 522 (see Fig. 33) is deployed into the prosthesis 500 to exert a pushing or punching force upon the head 512 of a given fastener 508. In the illustrated embodiment, the tool 522 comprises a catheter 524 that carries a punch member 526 at its distal end. In a desired arrangement, the distal end of the catheter 524 is steerable, to aid in establishing point contact between the punch member 526 and the head 512 of the given fastener 508. The head 512 can include a recess 528 to receive and stabilize the tip of the punch member 526 with respect to the head 512 during use (see Fig. 34).

In use, the punch member 526 is manipulated to apply a pushing or punching force upon the selected fastener head 512. As Figs. 35 and 36 show, the application of the pushing force by the punch member 526 forces the wings 516 and 518 against the near side of the vessel wall 34. The wings 516 and 518 are still in their closed condition, because the hinge region 520 is still confined within the grommet 510. The closed wings 516 and 518 form an obturator that penetrates tissue as it advances to the far side of the vessel wall. As the hinge region 510 is freed from the grommet 510 (Fig. 37), the wings 516 and 518 resiliently return to their spread-apart condition against the far side of the vessel wall. Upon removal of the punch member 526 (see Fig. 38), the head 512 and spread-apart wings 516 and 518 remain in their mutually opposed condition in the vessel wall, to secure

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the prosthesis 500 against the vessel wall. In use, the physician locates and manipulates the punch member 526 in succession against each fastener 508, to complete the anchorage of the prosthesis 500 to the vessel wall.

In one embodiment (see Fig. 39), each fastener 508 can include a tracking wire 530 that is releasably coupled to the head 512. The tracking wire 530 extends from the head 512 outside the body for access outside the vessel. In this arrangement, the punch member 526 includes a lumen to accommodate passage of the tracking wire 530. The tracking wire 530 guides the punch member 526 in an intraluminal path to the respective fastener 508. After the punch member 526 is manipulated to drive the fastener 508 into the vessel wall, the punch member 526 can be withdrawn over the tracking wire 530. The tracking wire 530 can be released from the now-secured head 512, e.g., by applying a moderate pulling force upon the tracking wire 530. The tracking wire 530 can then be withdrawn. The punch member 526 is sequentially guided over another tracking wire 530 for interaction with another one of the fasteners 508, until a desired degree of anchorage is achieved.

In an alternative embodiment, an integrated fastener assembly 502 on the prosthesis 500 can be used to temporarily tack the prosthesis 500 in place while a permanent anchoring technique is carried out. For example, in this arrangement, after using the integrated fastener assembly 502 to temporarily hold the prosthesis 500 in a desired location, the separate helical fasteners 28 are deployed in the manner previously described, to permanently anchor the prosthesis 500 against the vessel wall.

It will be appreciated that the components and/or features of the preferred embodiments described herein may be used together or separately, while the depicted

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methods and devices may be combined or modified in whole or in part. It is contemplated that the components of the directing device, fastener applier and helical fastener may be alternately oriented relative to each other, for example, offset, bi-axial, etc. Further, it will be understood that the various embodiments may be used in additional procedures not described herein, such as vascular trauma, arterial dissections, artificial heart valve attachment and attachment of other prosthetic device within the vascular system and generally within the body.

The preferred embodiments of the invention are described above in detail for the purpose of setting forth a complete disclosure and for the sake of explanation and clarity. Those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

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We Claim:

1. A fastening system for implanting a fastener in a hollow body organ comprising:

a fastener attachment assembly sized and configured to be deployed within a hollow body organ and including an actuated member that is selectively operable to generate an implantation force to implant a fastener into tissue within the hollow body organ, and

means associated with the fastener attachment assembly for applying a resolving force to resolve at least a portion of the implantation force within the hollow body organ.

2. A fastening system for implanting a fastener in a targeted endovascular region comprising

a fastener attachment assembly sized and configured to be deployed within the targeted endovascular region and including an actuated member that is selectively operable to generate an implantation force to implant a fastener into tissue in the targeted endovascular region, and

means associated with the fastener attachment assembly for applying a resolving force to resolve at least a portion of the implantation force within the targeted endovascular region.

3. A fastening system according to claim 1 or 2 wherein the means includes a stabilizing member.

4. A fastening system according to claim 3 wherein the stabilizing member includes a strut assembly.

5. A fastening system according to claim 3 wherein the stabilizing member includes a spring-loaded arm adapted for contact with tissue.

6. A fastening system according to claim 3 wherein the stabilizing member includes an expandable member adapted for contact with tissue.

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7. A fastening system according to claim 3 wherein the stabilizing member includes a tissue grasping element.

8. A fastener system according to claim 1 or 2 wherein the fastener attachment assembly includes a fastener applier component that carries the actuated member and a guide component having a lumen accommodating passage of the fastener applier and the actuated member, and

wherein the means is associated with the guide component.

9. A fastening system according to claim 8 wherein the means includes a stabilizing member carried by the guide component.

10. A fastener system according to claim 9 wherein the stabilizing member includes a strut assembly on the guide component.

11. A fastening system according to claim 9 wherein the stabilizing member includes a spring-loaded arm on the guide component adapted for contact with tissue.

12. A fastening system according to claim 9 wherein the stabilizing member includes an expandable member on the guide component adapted for contact with tissue.

13. A fastener system according to claim 9 wherein the stabilizing member includes a tissue grasping element on the guide component.

14. A fastening system according to claim 8 wherein the guide component includes a deflectable distal region.

15. A fastening system according to claim 1 or 2 wherein the fastener attachment assembly includes a fastener applier component that carries the actuated member and a guide component having a lumen accommodating

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passage of the fastener applier and the actuated member, and

wherein the means associated with the fastener applier component.

16. A fastening system according to claim 15 wherein the means includes a stabilizing member carried by the fastener applier component.

17. A fastener system according to claim 16 wherein the stabilizing member includes a strut assembly on the fastener applier component.

18. A fastening system according to claim 16 wherein the stabilizing member includes a spring-loaded arm on the fastener applier component adapted for contact with tissue.

19. A fastening system according to claim 16 wherein the stabilizing member includes an expandable member on the fastener applier component adapted for contact with tissue.

20. A fastener system according to claim 16 wherein the stabilizing member includes a tissue grasping element on the fastener applier component.

21. A fastening system according to claim 1 or 2 wherein the actuated member comprises a driven member for implanting a helical fastener.

22. A fastening system according to claim 1 or 2 wherein the fastener attachment assembly includes a fastener applier component that carries the actuated member, and

wherein the means is associated with the fastener applier component.

23. A fastening system according to claim 22 wherein the fastener applier component includes a catheter body that carries the actuated member, the catheter body having a column strength, and

wherein the means includes, at least in part, the

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column strength of the catheter body.

24. A fastening system according to claim 22 wherein the fastener applier component includes a catheter body that carries the actuated member, and wherein the means includes, at least in part, a stabilization member carried by the catheter body.

25. A fastener system according to claim 24 wherein the stabilizing member includes a strut assembly on the catheter body.

26. A fastening system according to claim 24 wherein the stabilizing member includes a spring-loaded arm on the catheter body adapted for contact with tissue.

27. A fastening system according to claim 24 wherein the stabilizing member includes an expandable member on the catheter body adapted for contact with tissue.

28. A fastener system according to claim 24 wherein the stabilizing member includes a tissue grasping element on the catheter body.

29. A fastener system according to claim 1 or 2 wherein the fastener attachment assembly includes a fastener applier component that carries the actuated member, and

wherein the means includes a stabilization device separate from the fastener applier component that works in cooperation with the fastener applier component.

30. A fastening system according to claim 1 or 2 wherein the fastener attachment assembly includes a guide component for the actuated member, and wherein the means is associated with the guide component.

31. A fastening system according to claim 30 wherein the guide component has a column strength, and

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wherein the means includes, at least in part, the column strength of the guide component.

32. A fastening system according to claim 30 wherein the means includes, at least in part, a stabilization member carried by the guide component.

33. A fastener system according to claim 32 wherein the stabilizing member includes a strut assembly on the guide component.

34. A fastening system according to claim 32 wherein the stabilizing member includes a spring-loaded arm on the guide component adapted for contact with tissue.

35. A fastening system according to claim 32 wherein the stabilizing member includes an expandable member on the guide component adapted for contact with tissue.

36. A fastener system according to claim 32 wherein the stabilizing member includes a tissue grasping element on the guide component .

37. A fastener system according to claim 1 or 2 wherein the fastener attachment assembly includes a guide component for the actuated member, and wherein the means includes a stabilization device separate from the guide component that works in cooperation with the guide component.

38. A method for implanting a fastener in a hollow body cavity comprising the steps of

deploying in a hollow body organ a fastener attachment assembly that includes an actuated member that is selectively operable to generate an implantation force to implant a fastener into tissue within the hollow body organ, and

applying a resolving force at or near the actuated member to resolve at least a portion of the implantation force within the hollow body organ.

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39. A method for implanting a fastener in a targeted endovascular region comprising the steps of
deploying by intraluminal passage into the targeted endovascular region a fastener attachment assembly that includes an actuated member that is selectively operable to generate an implantation force to implant a fastener into tissue in the targeted endovascular region, and
applying a resolving force at or near the actuated member to resolve at least a portion of the implantation force within the targeted endovascular region.

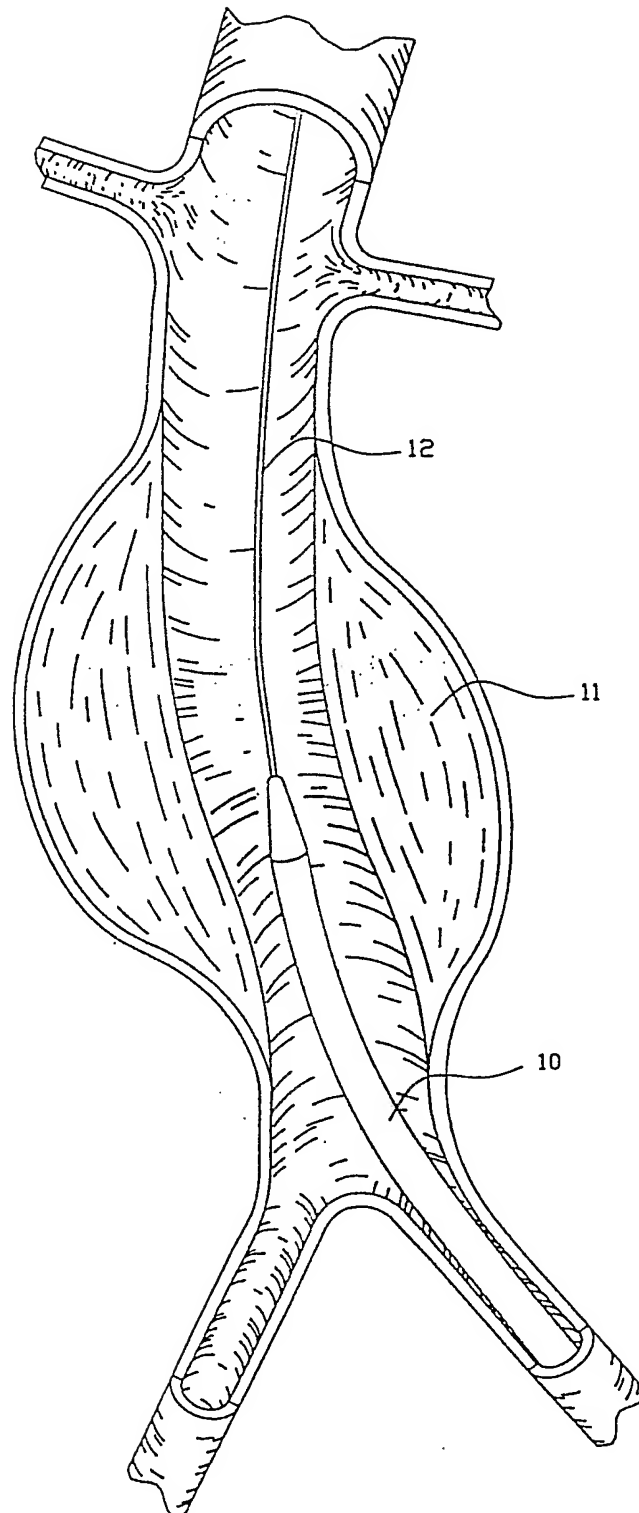


Fig. 1

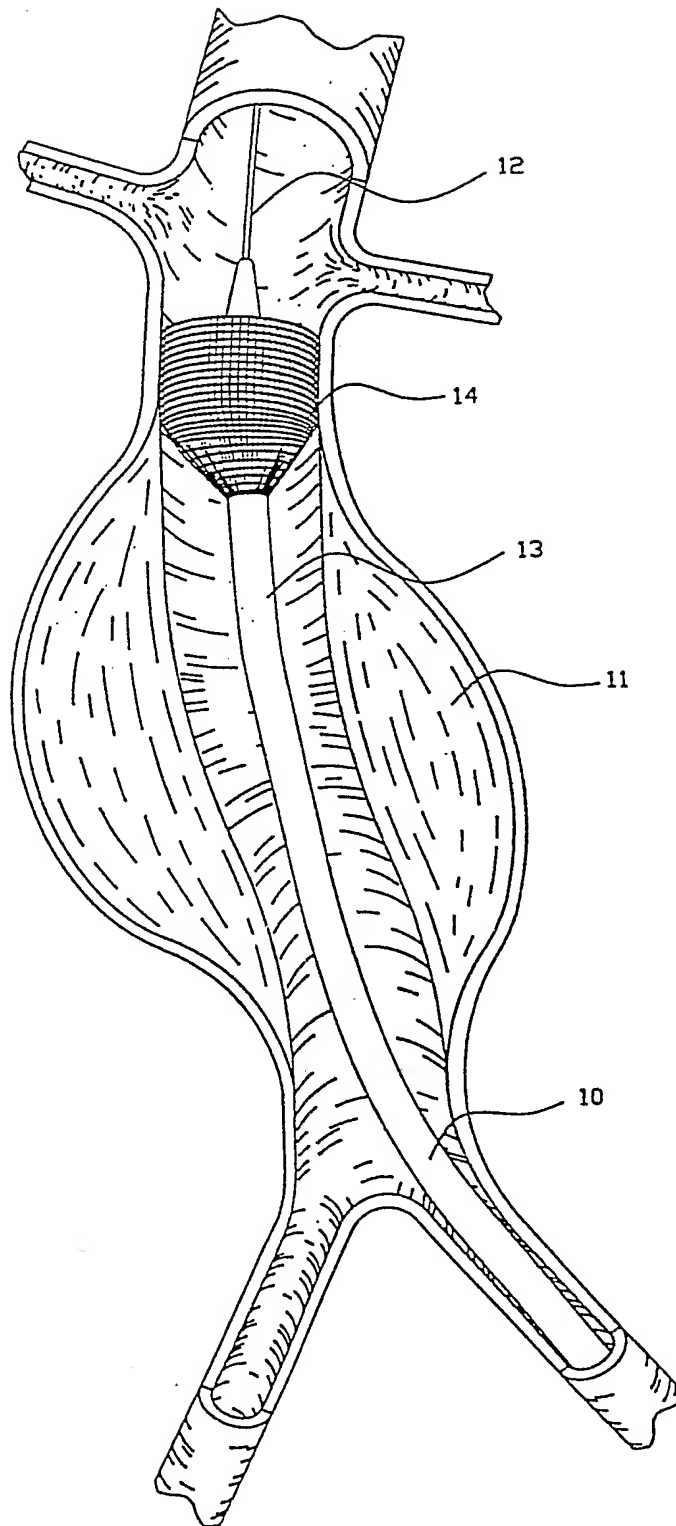


Fig. 2

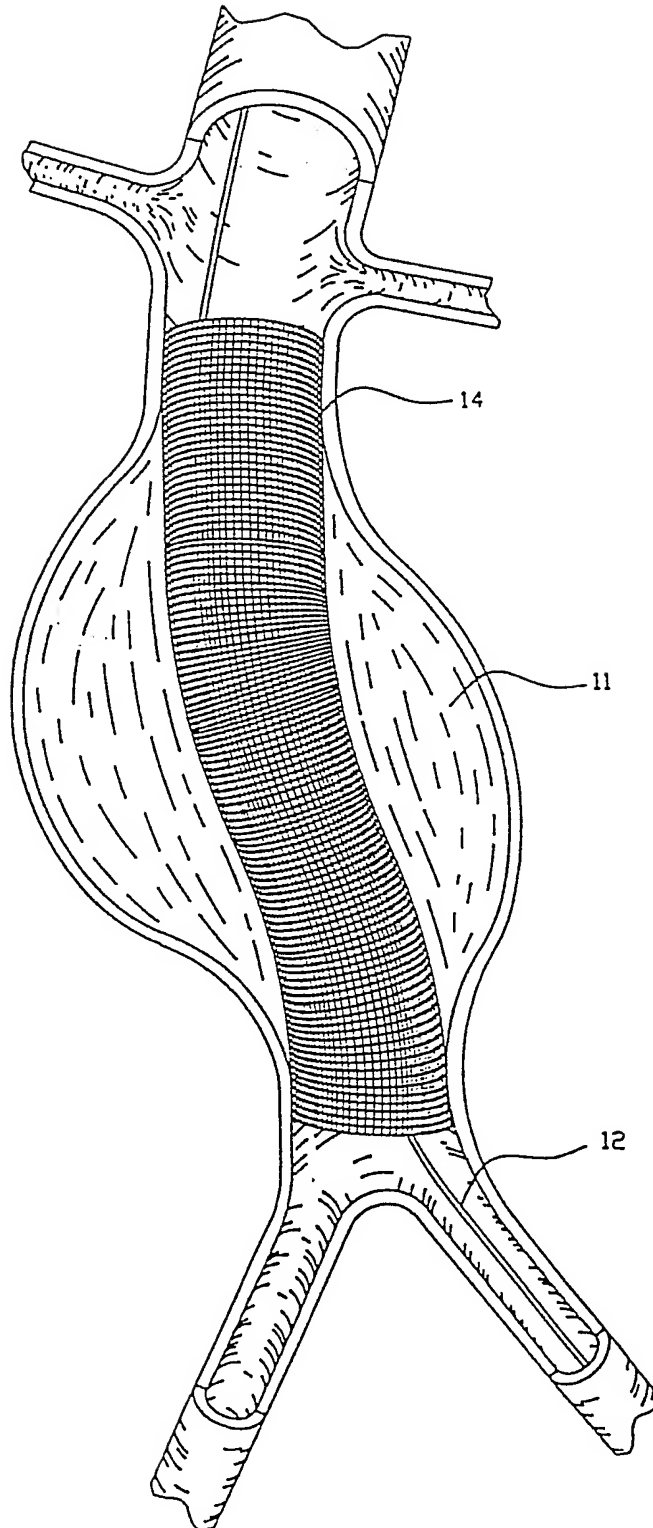


Fig. 3

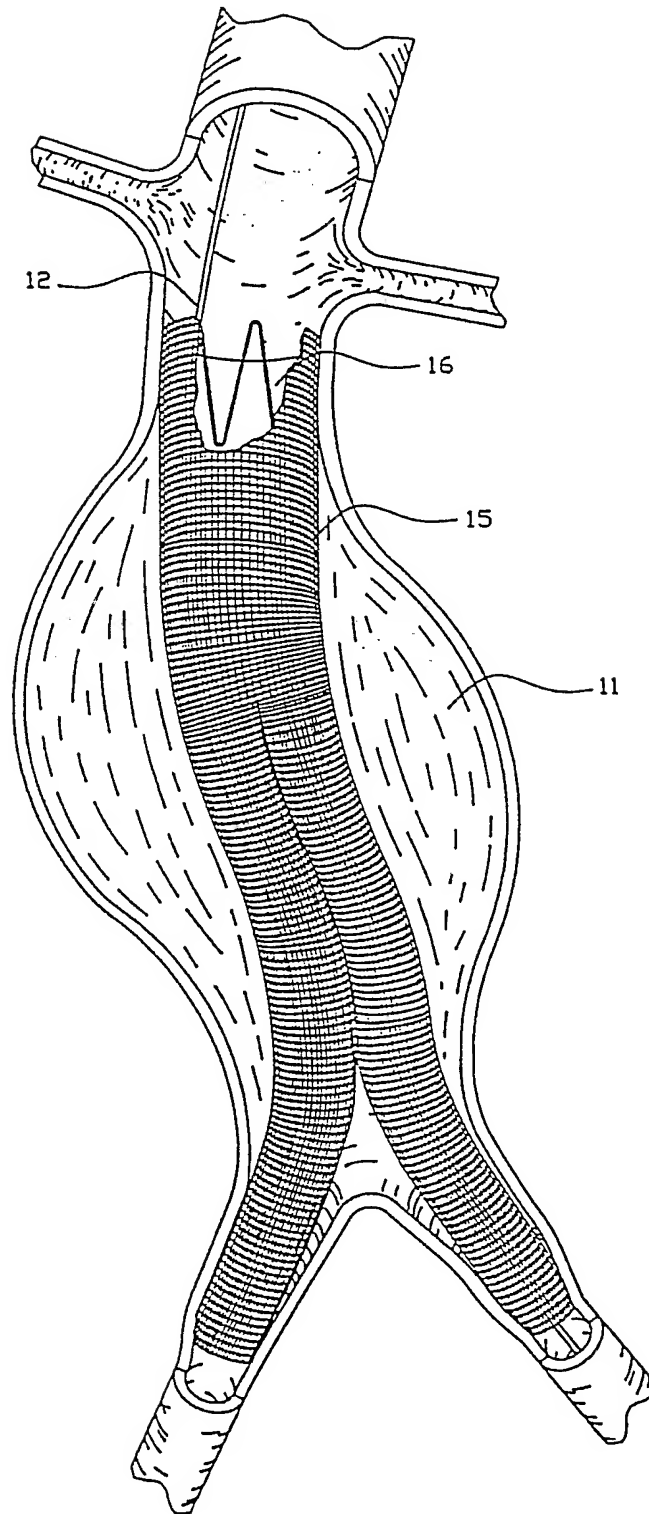


Fig. 4

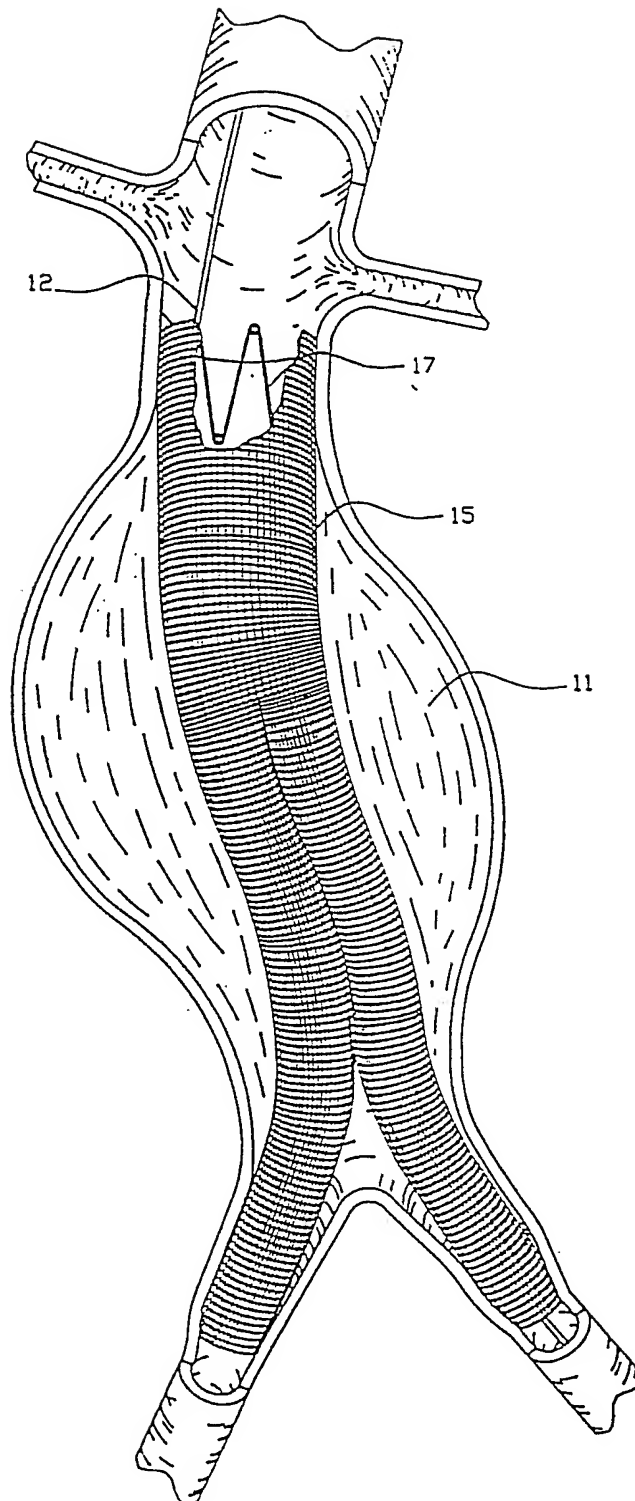


Fig. 5

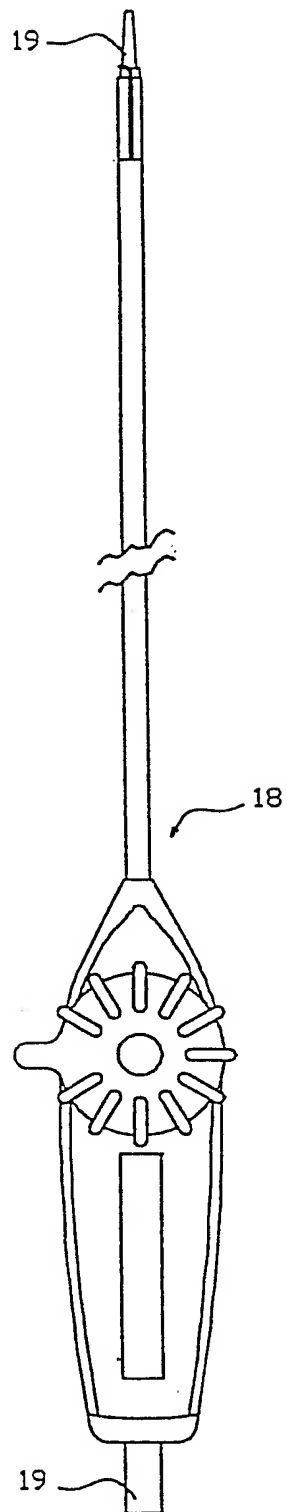


Fig. 6

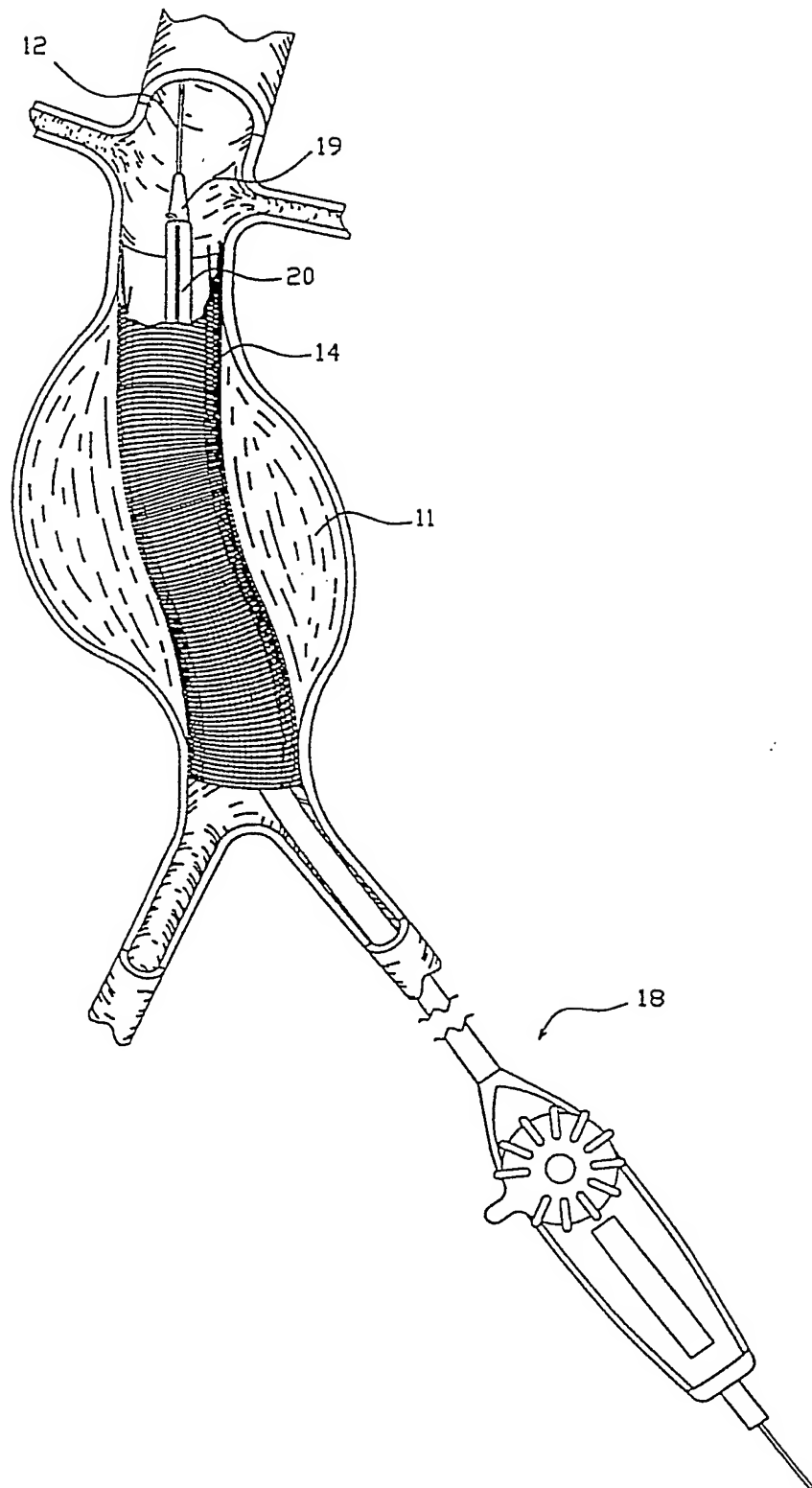


Fig. 7

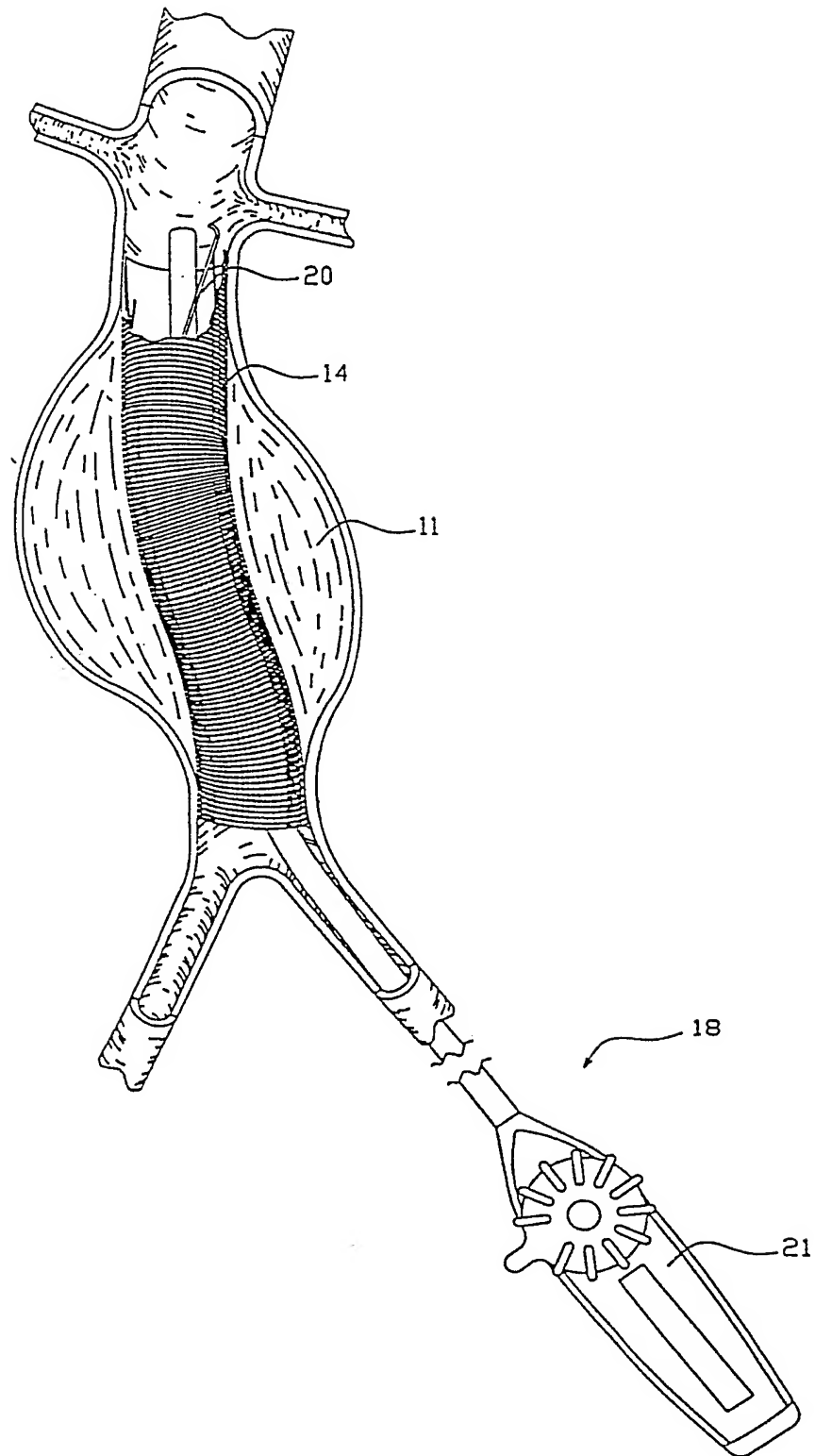


Fig. 8

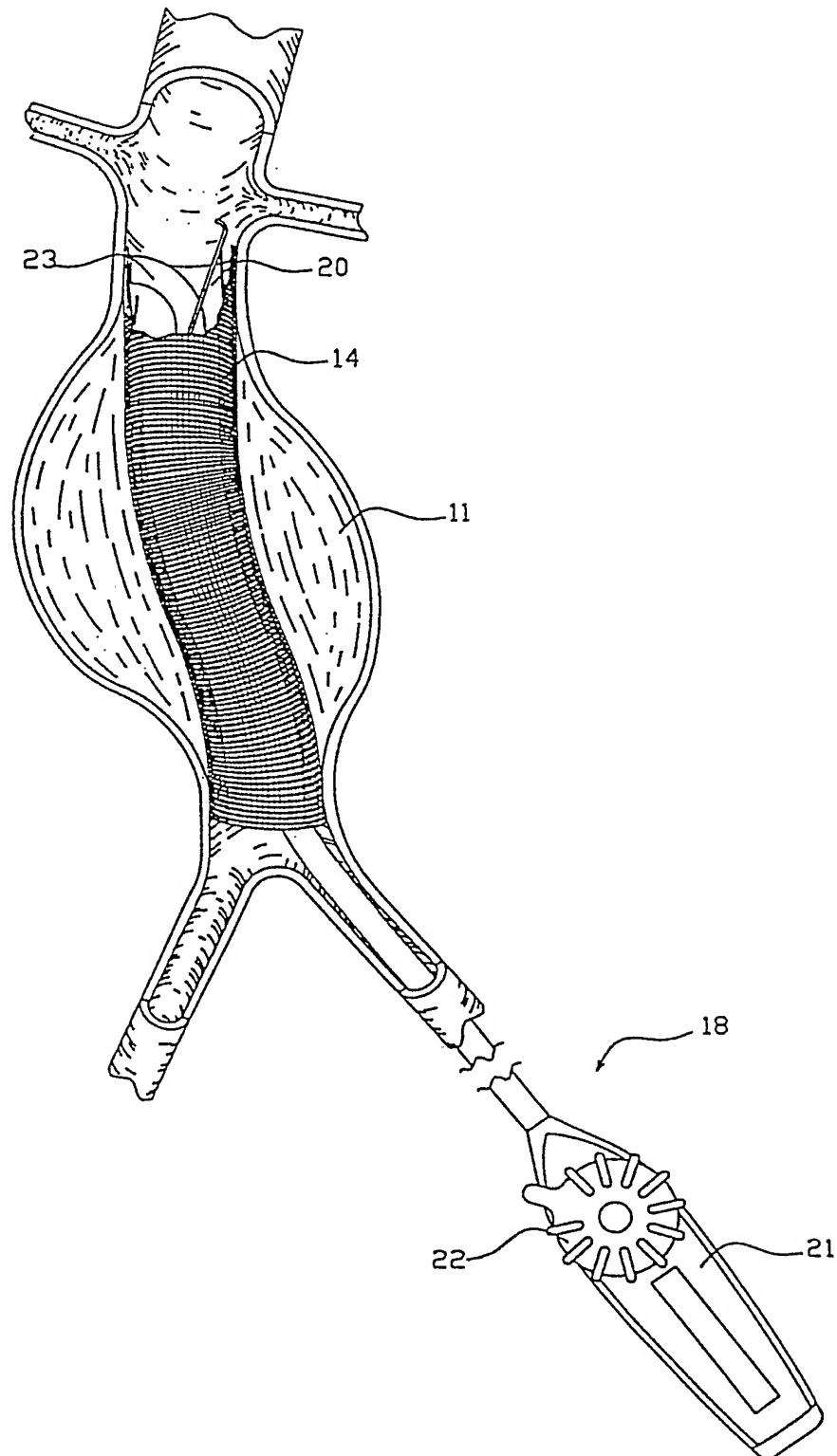


Fig. 9

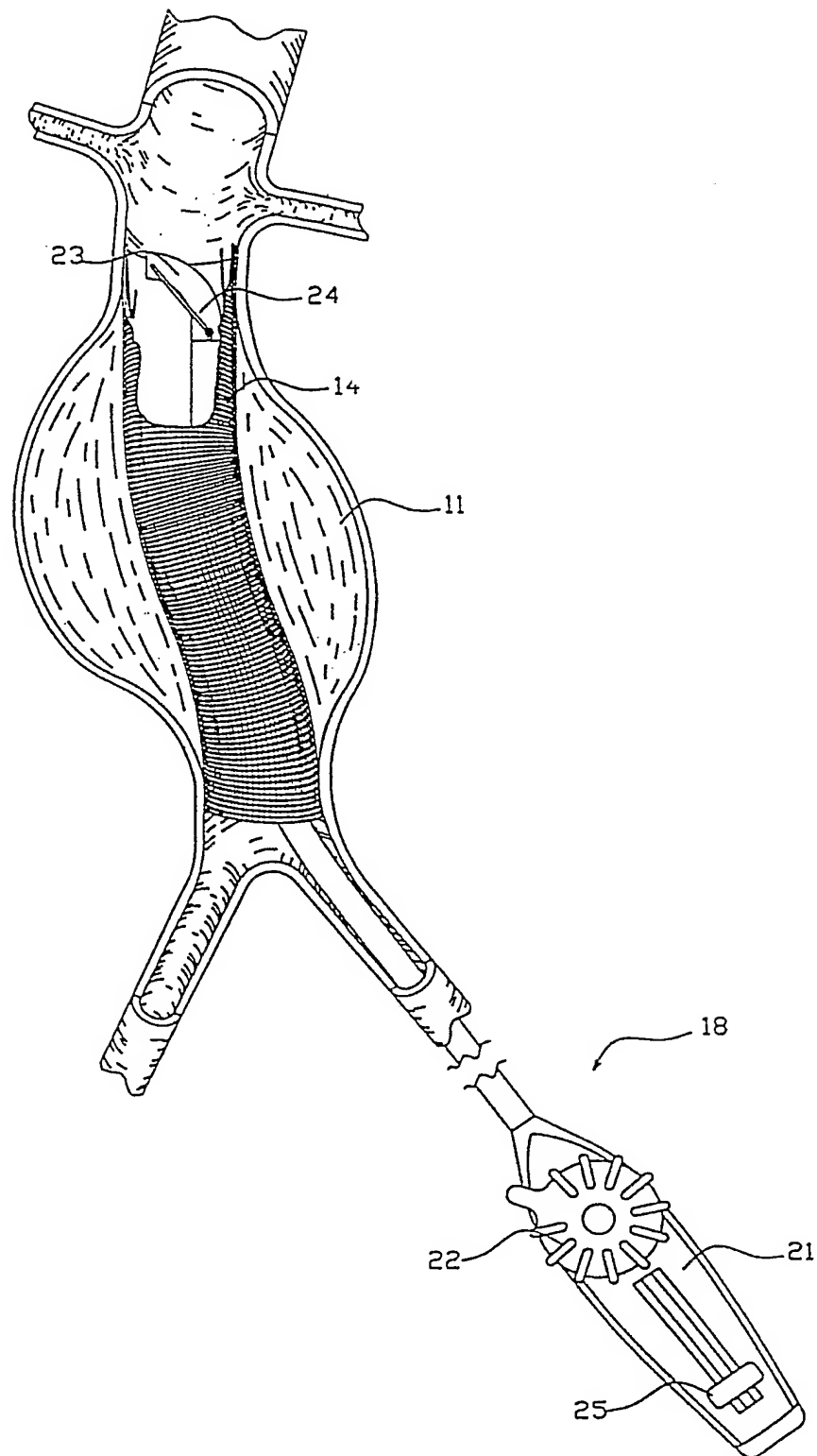


Fig. 10

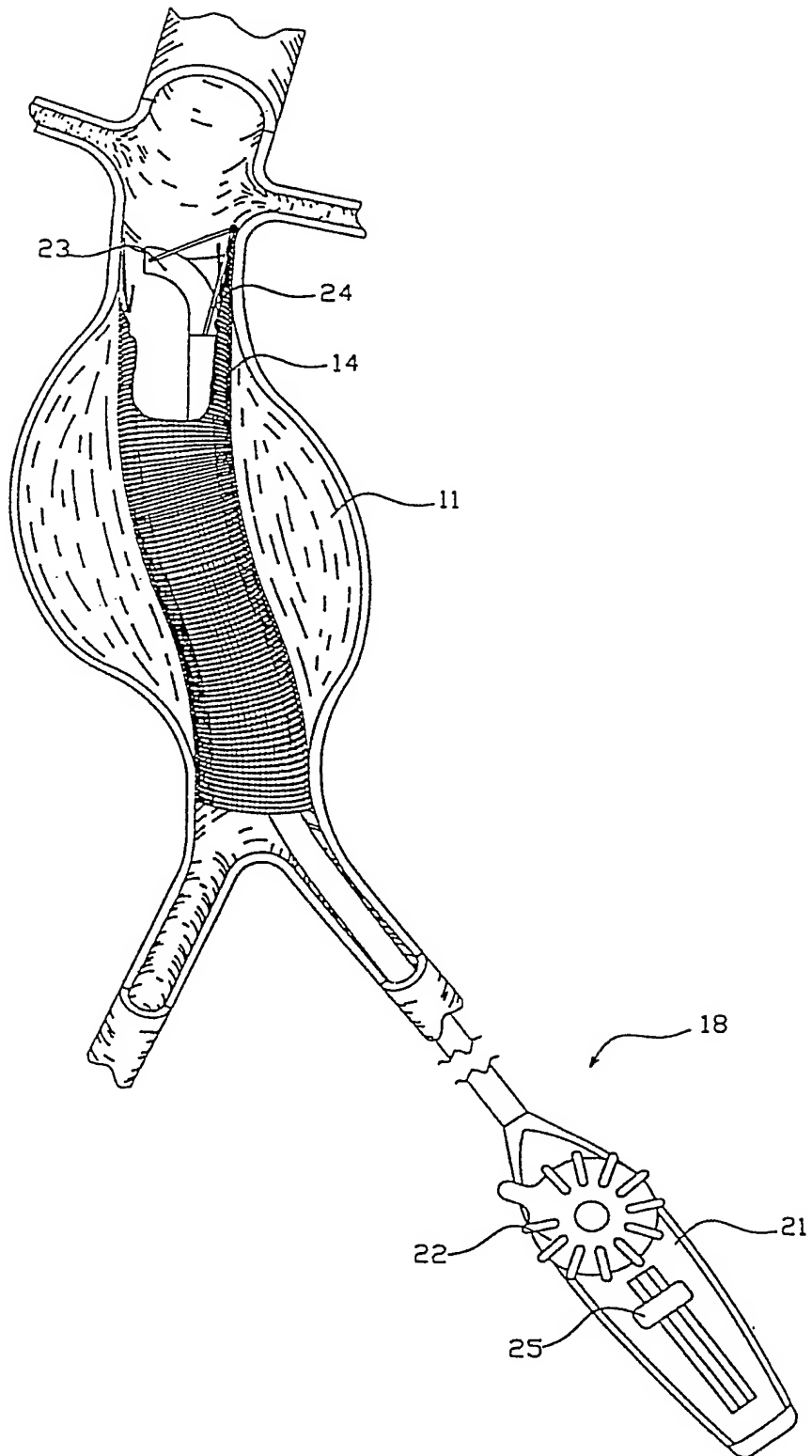


Fig. 11

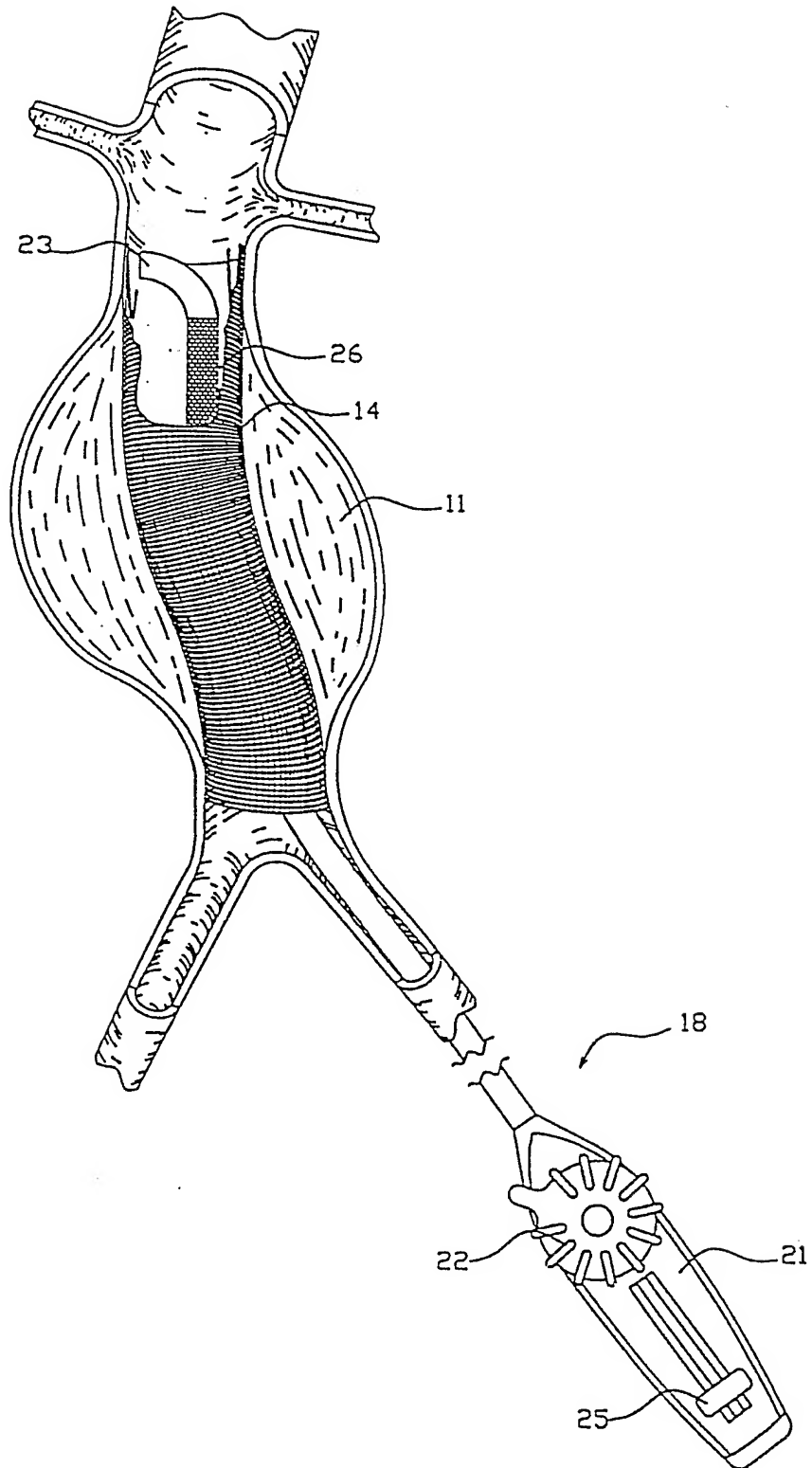


Fig. 12

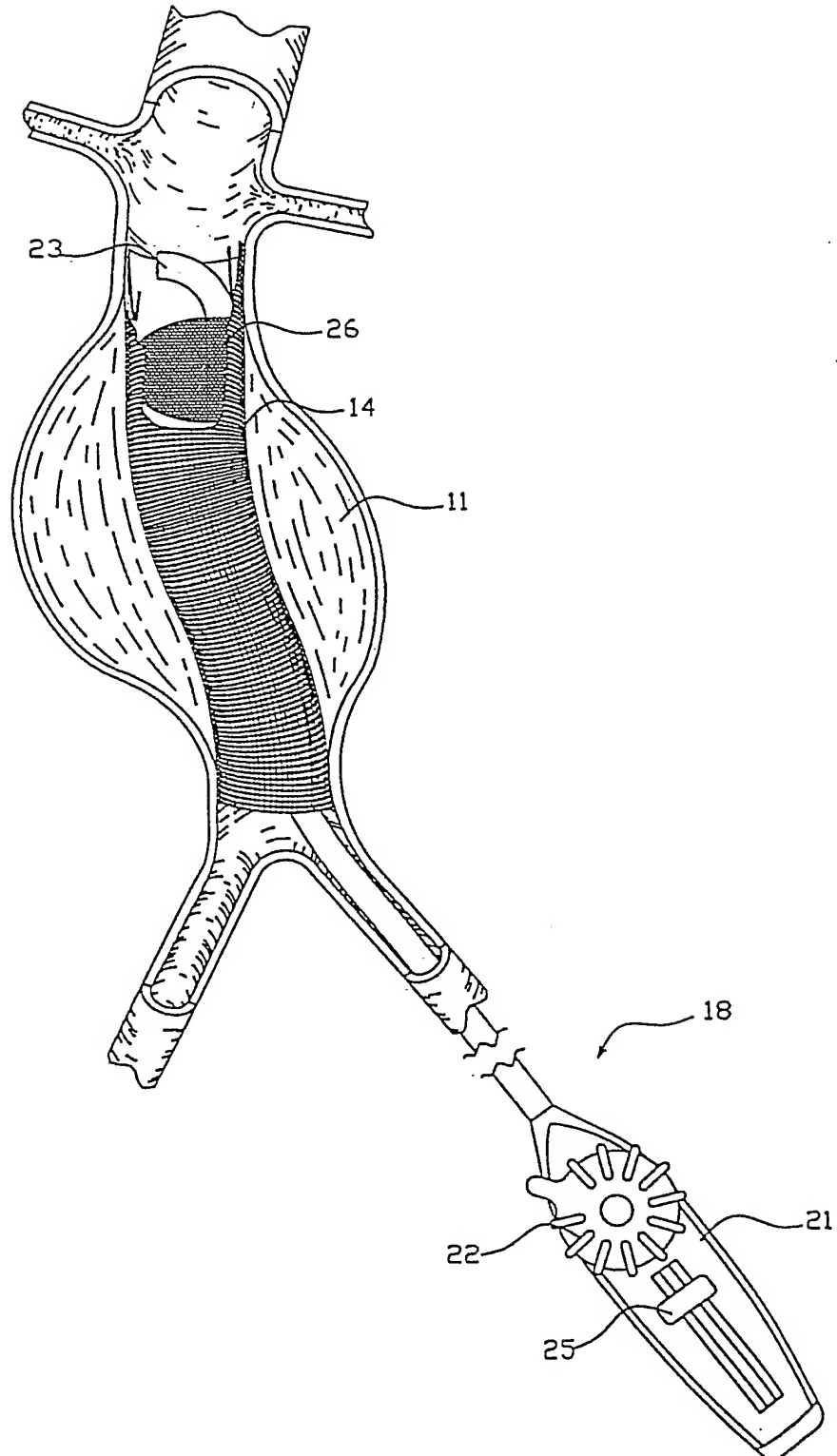


Fig. 13

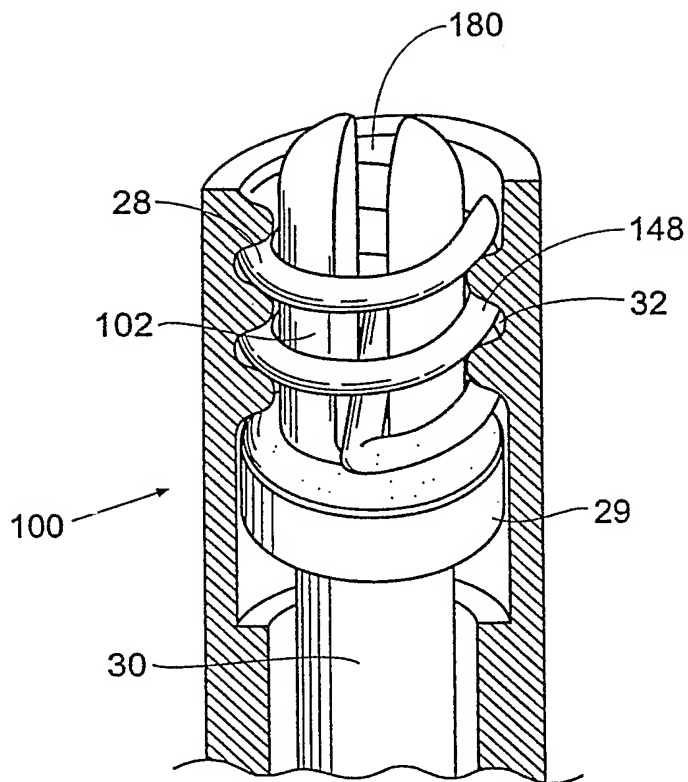


Fig. 14A

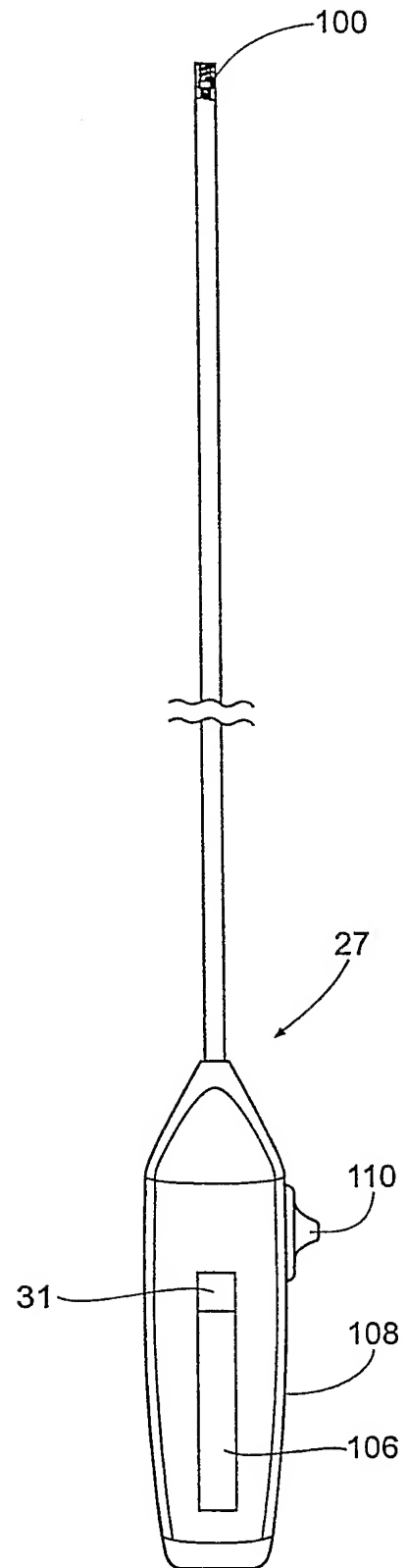
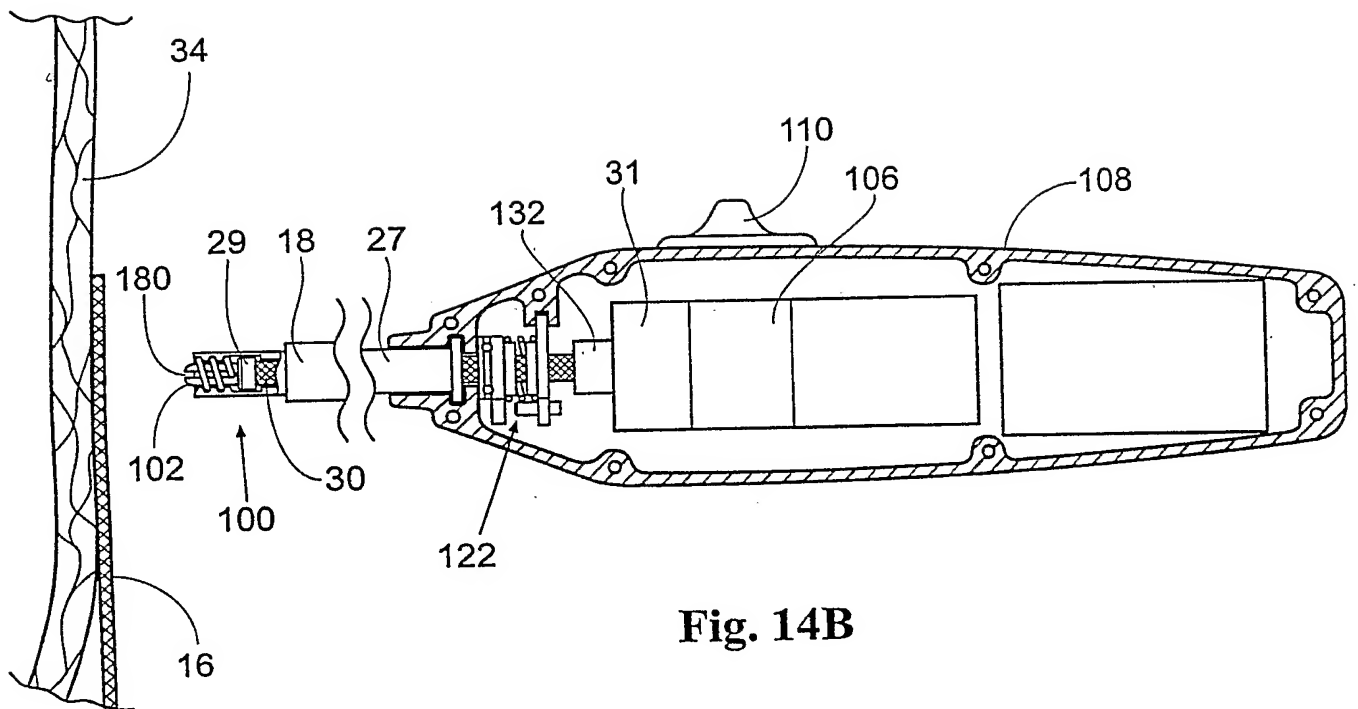


Fig. 14



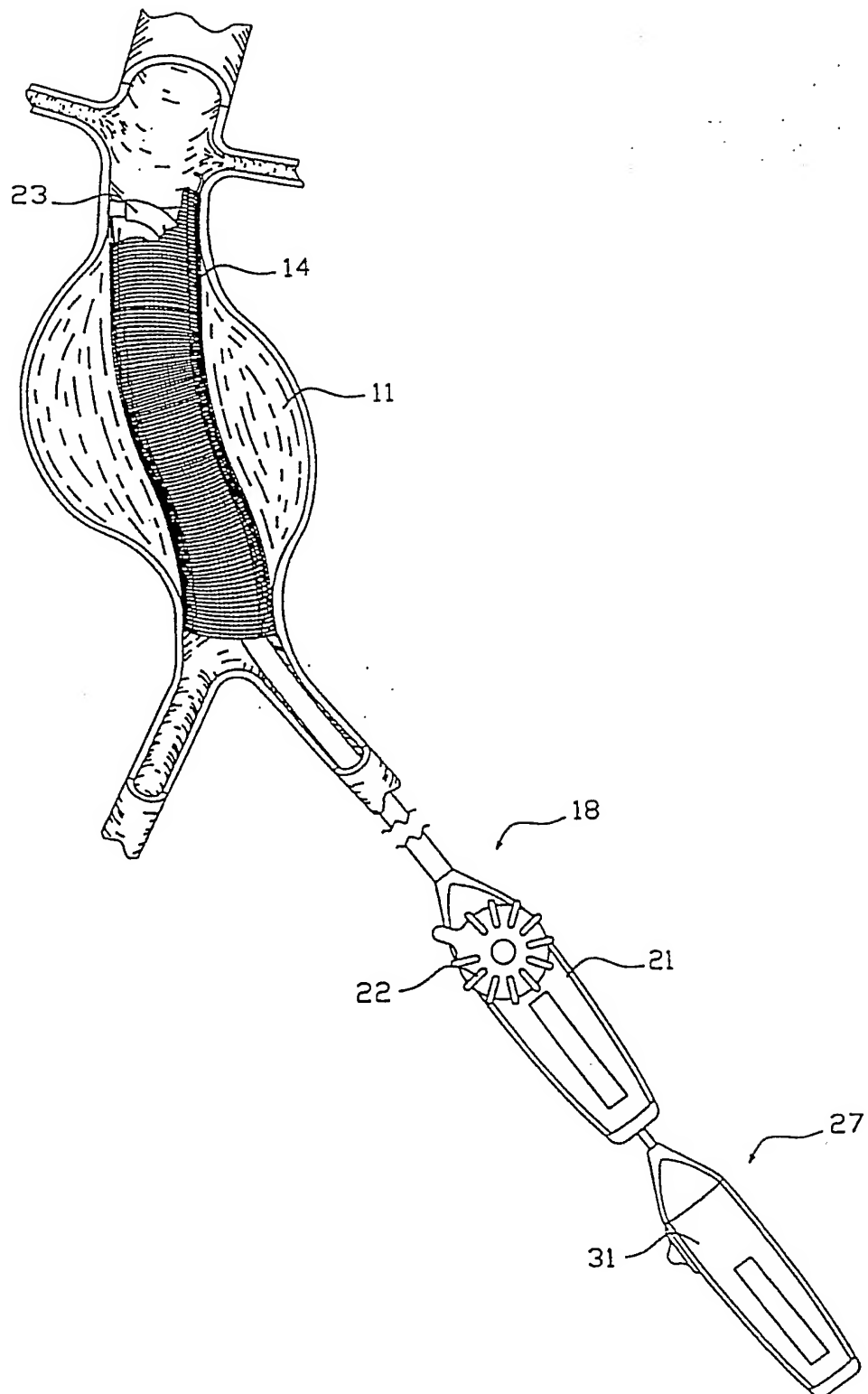


Fig. 15

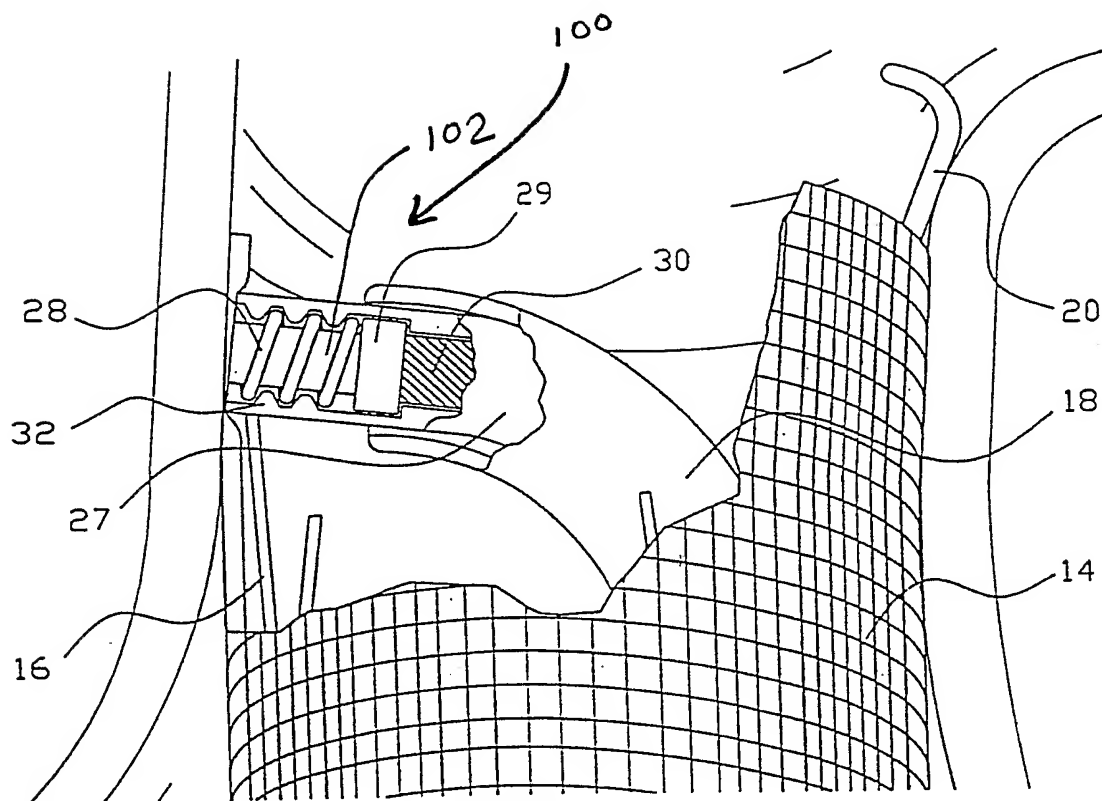


Fig. 16

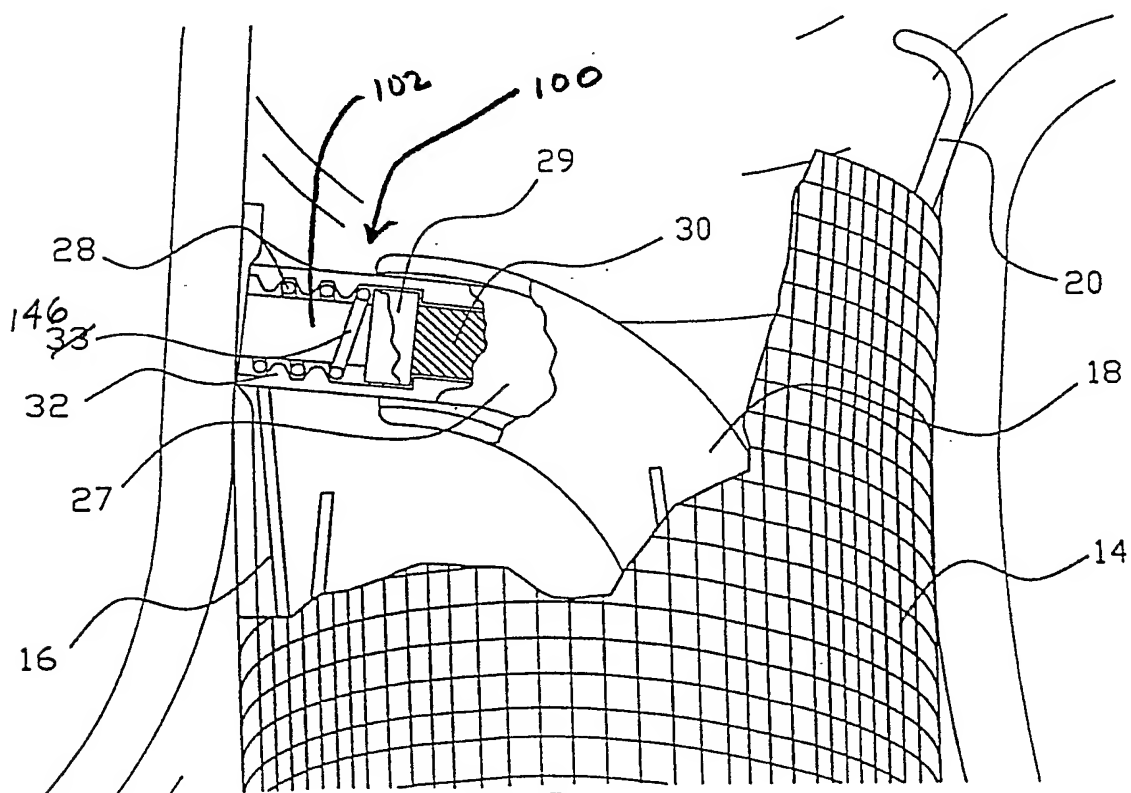


Fig. 17

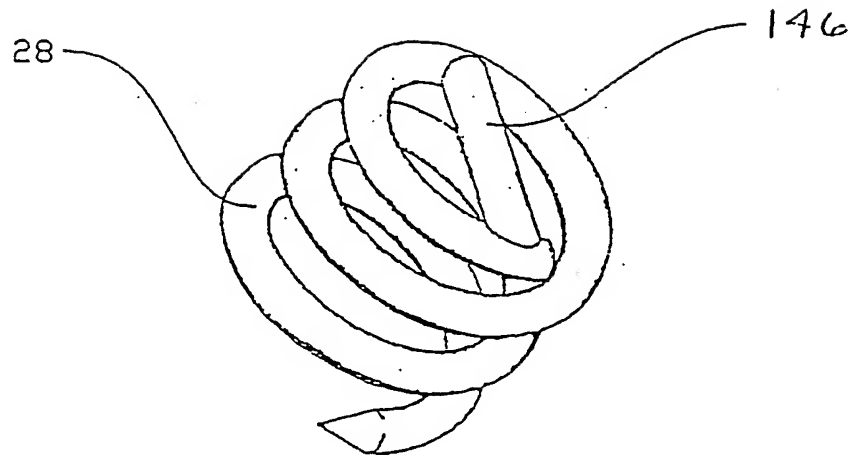


Fig. 18

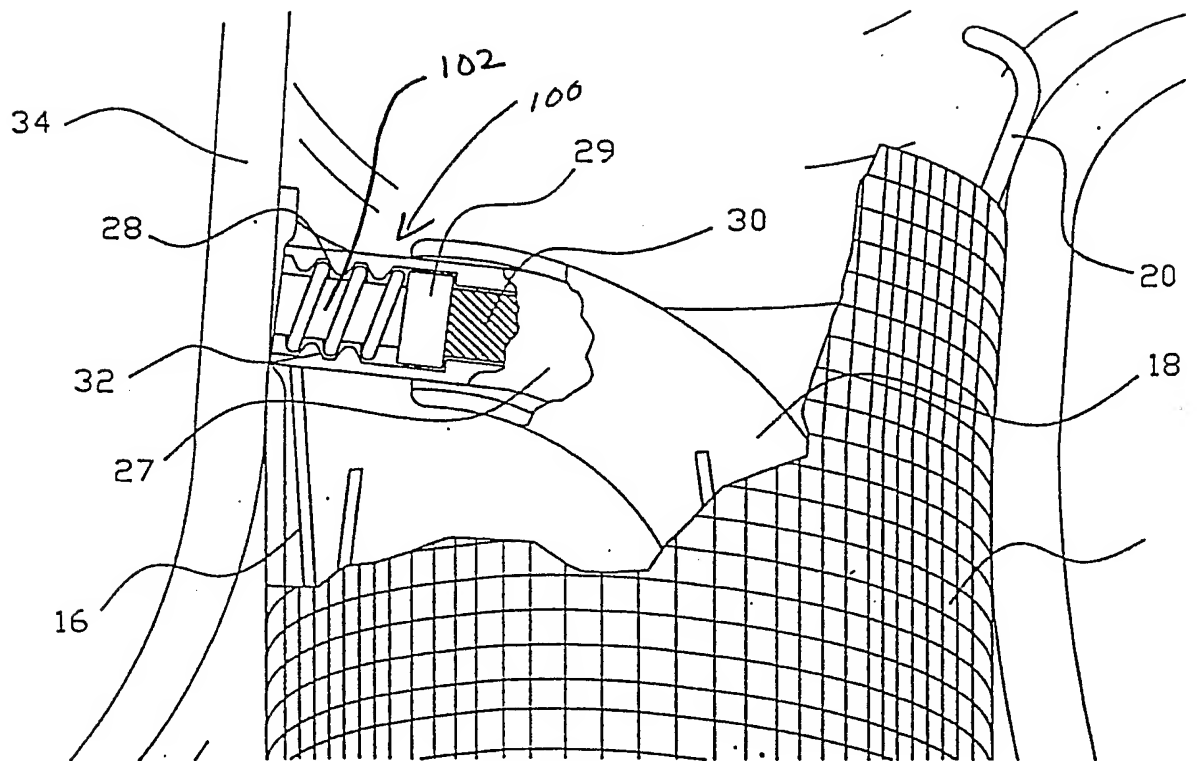


Fig. 19

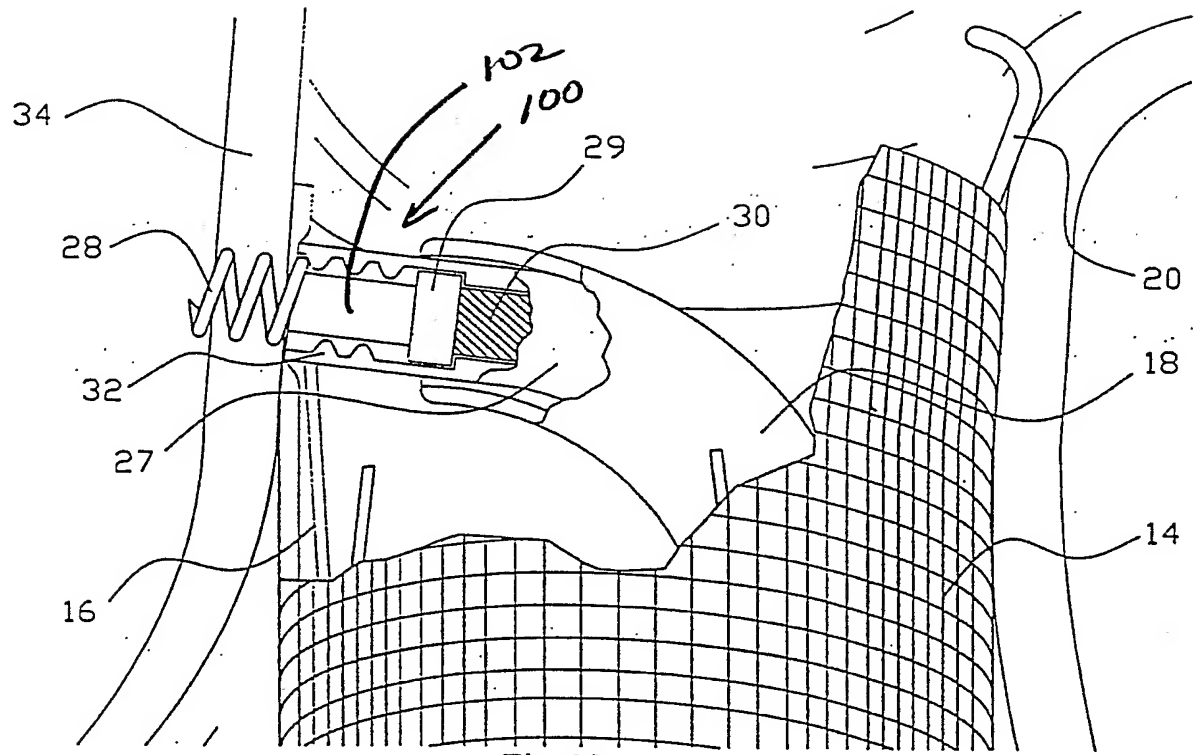


Fig. 20

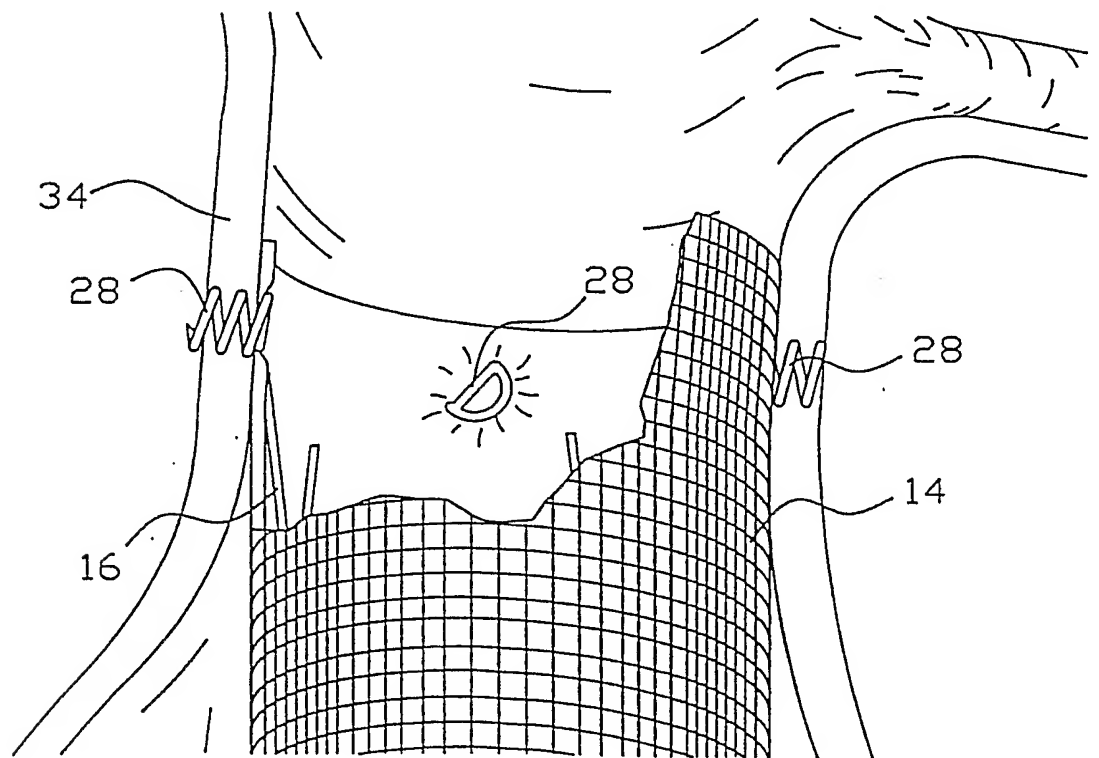


Fig. 21

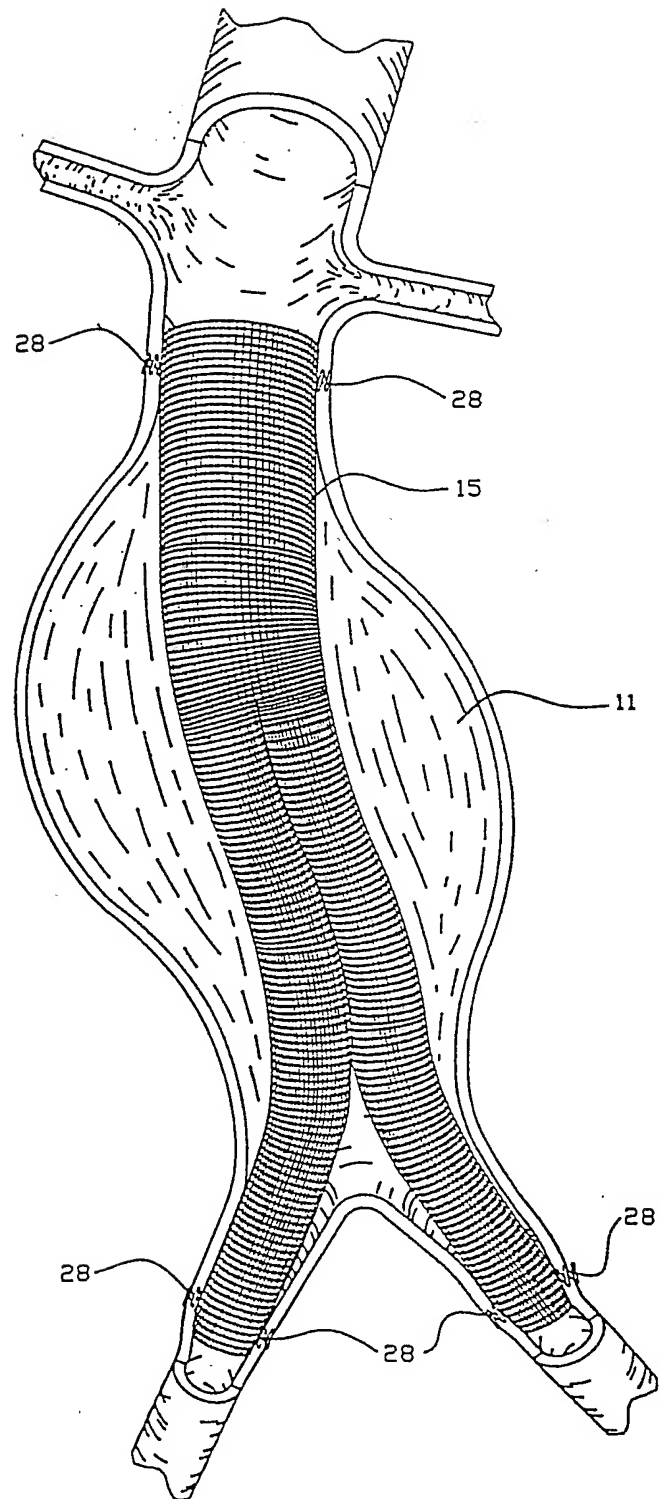


Fig. 22

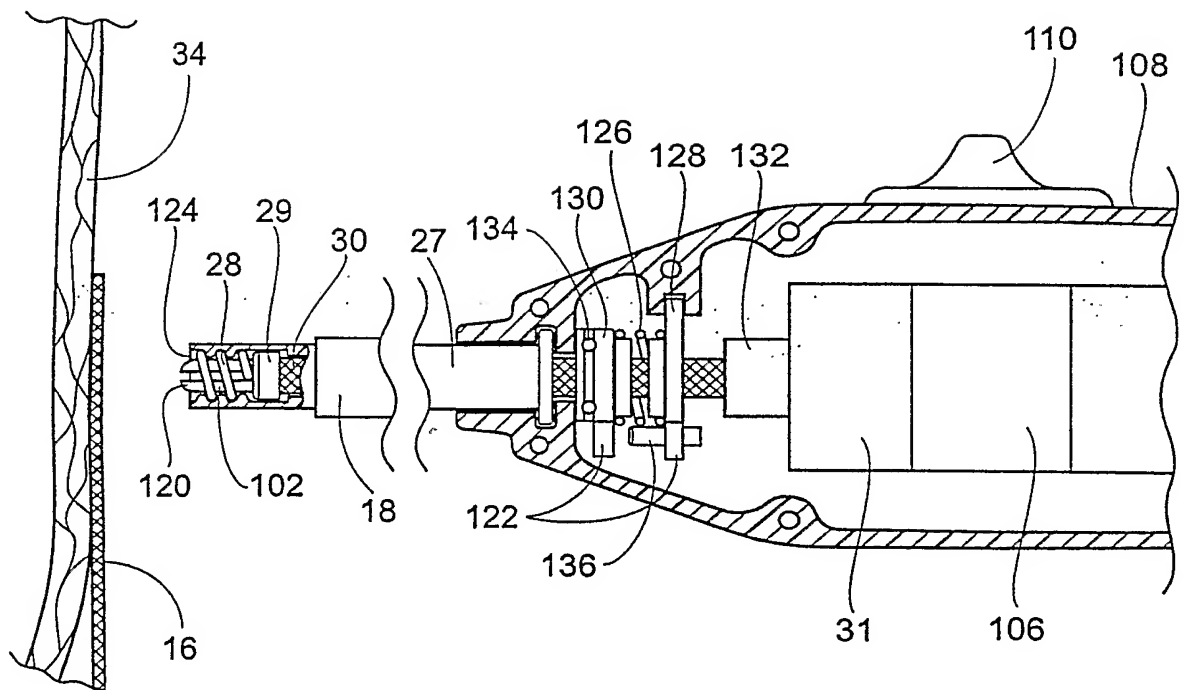


Fig. 23

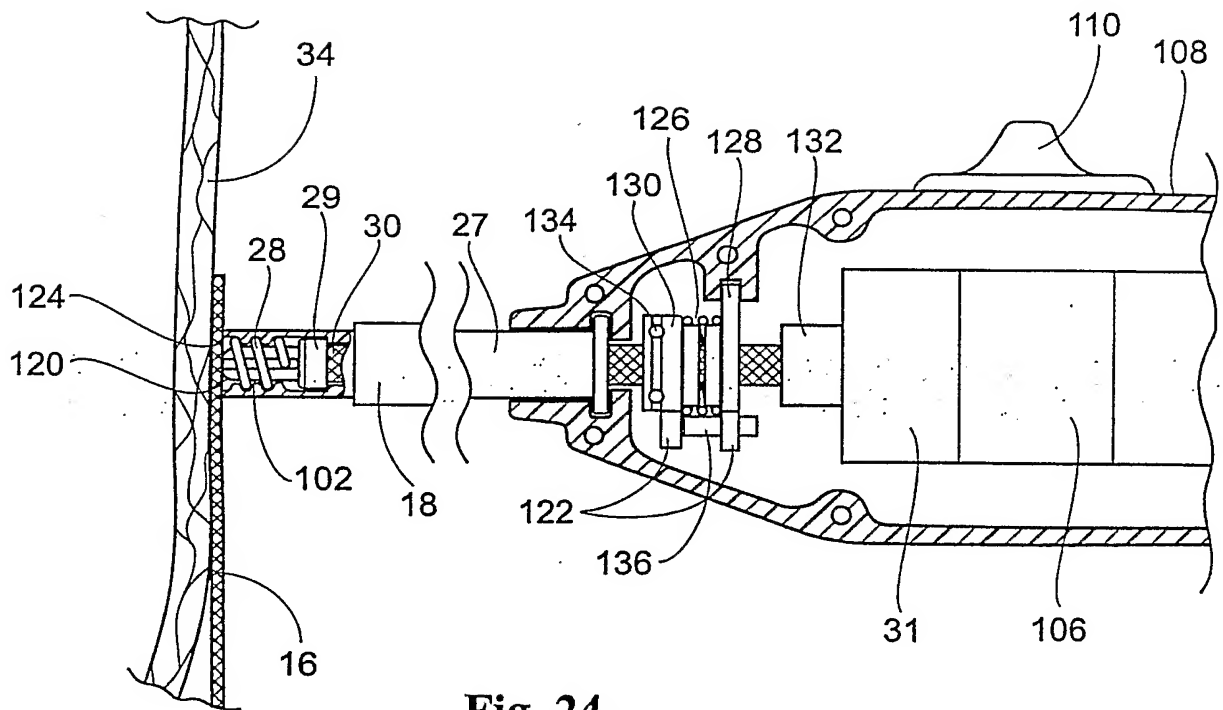


Fig. 24

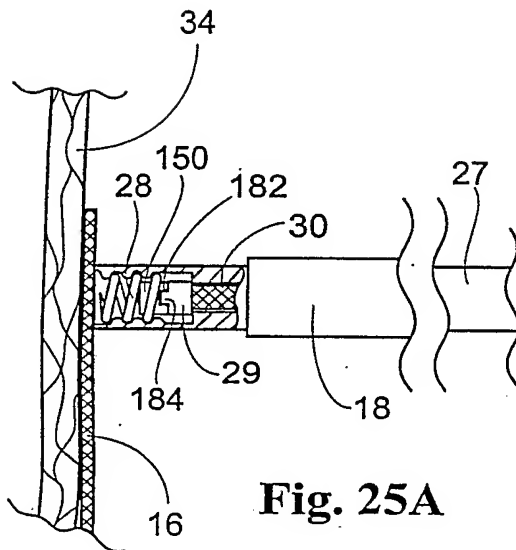


Fig. 25A

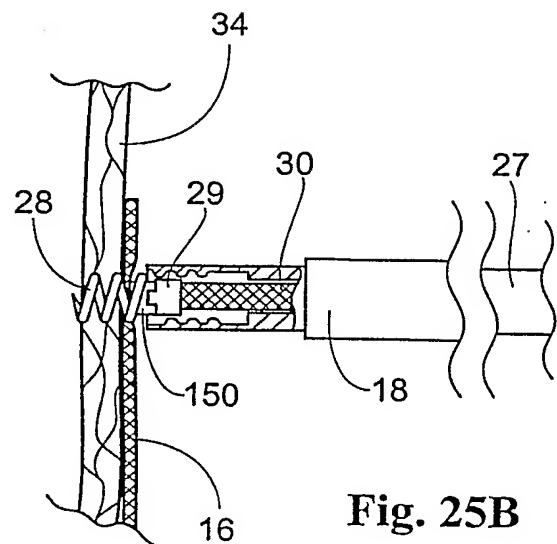


Fig. 25B

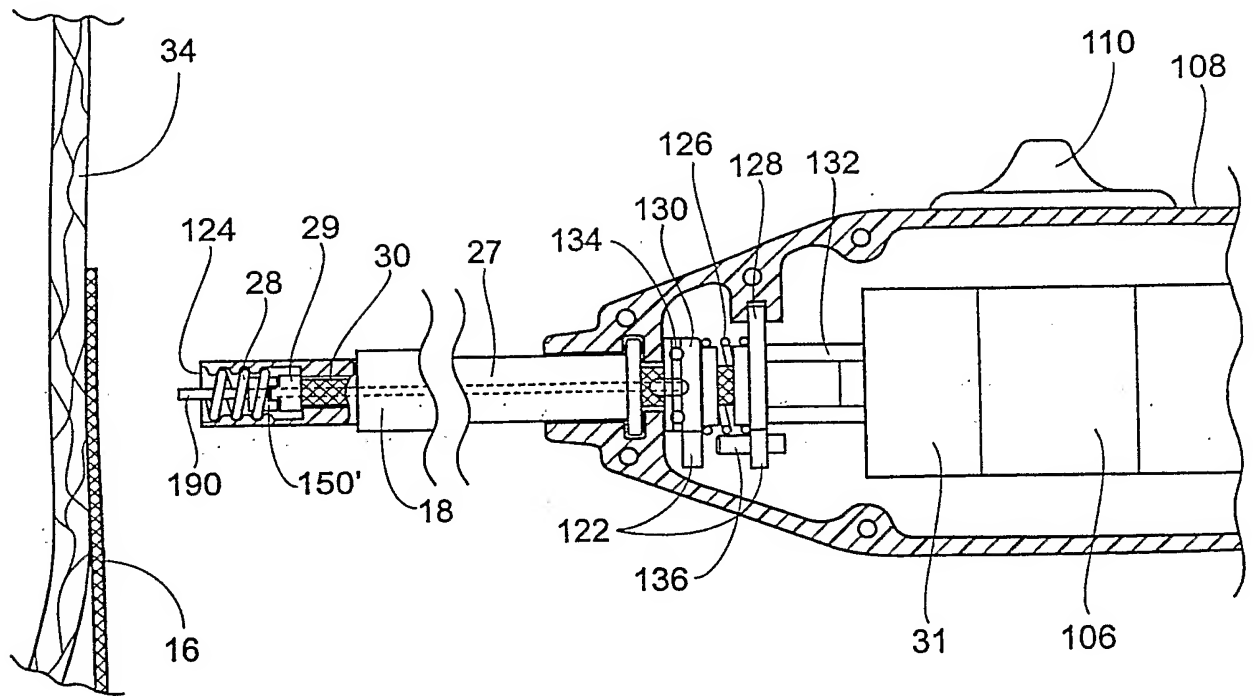


Fig. 26A

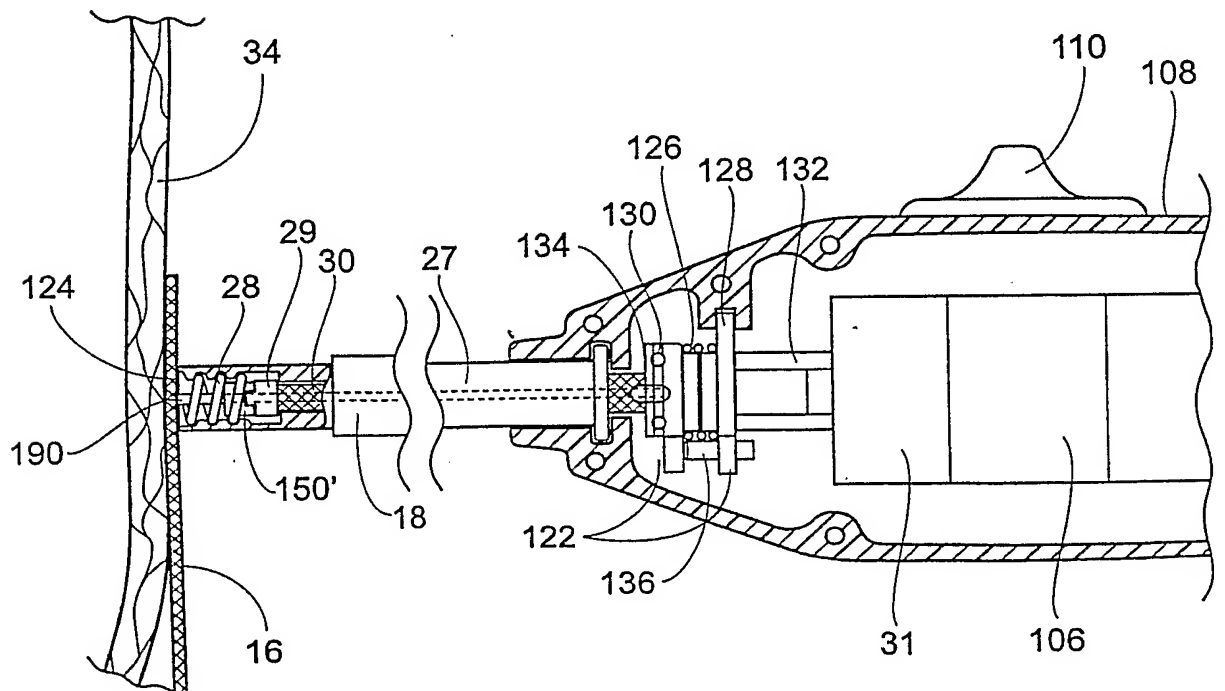
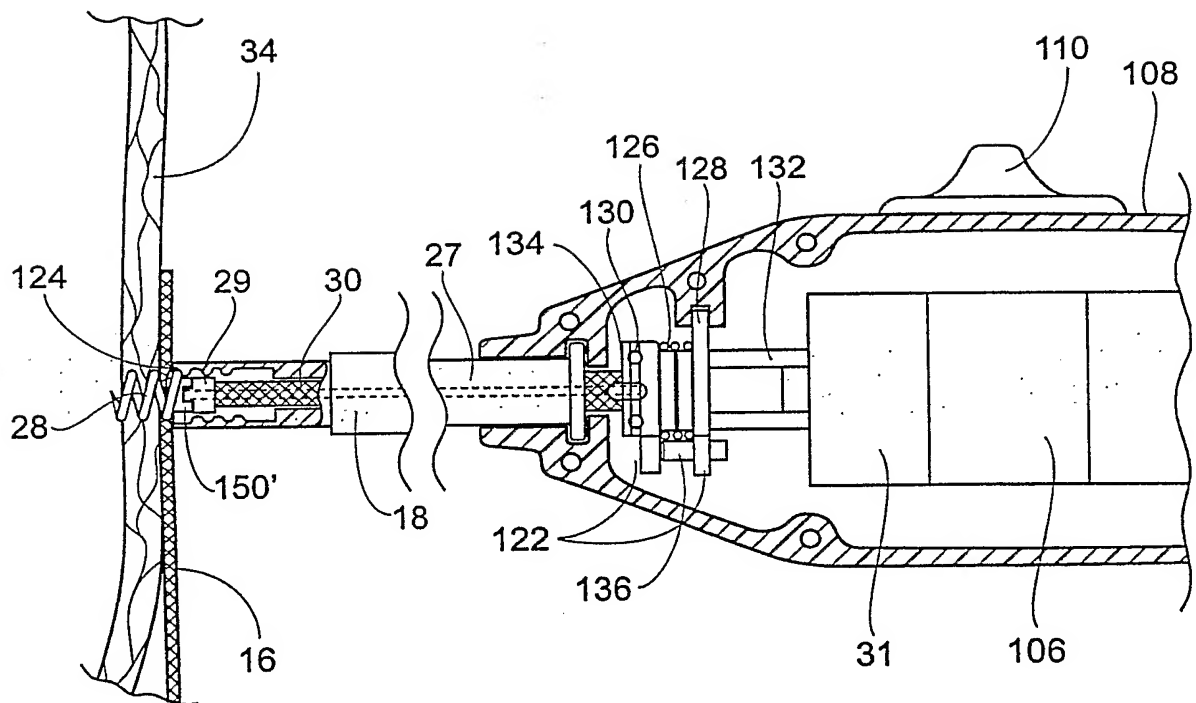


Fig. 26B

**Fig. 26C**

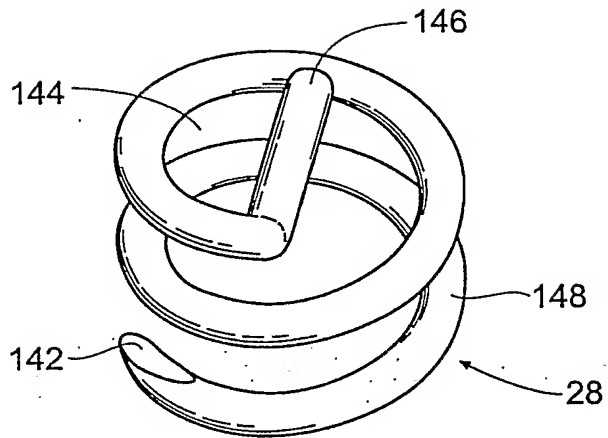


Fig. 27

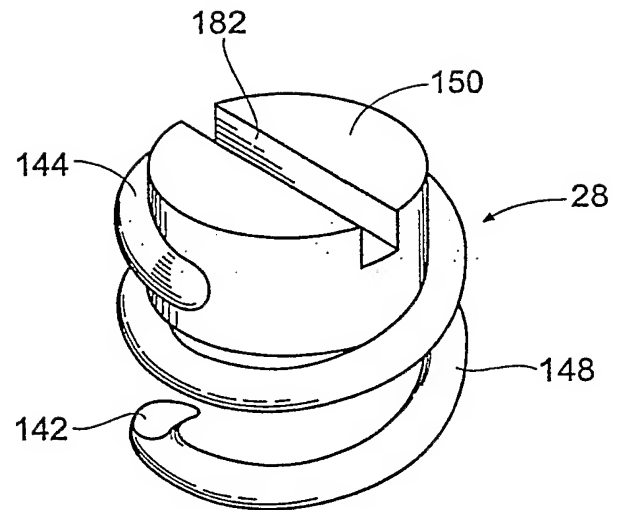


Fig. 28A

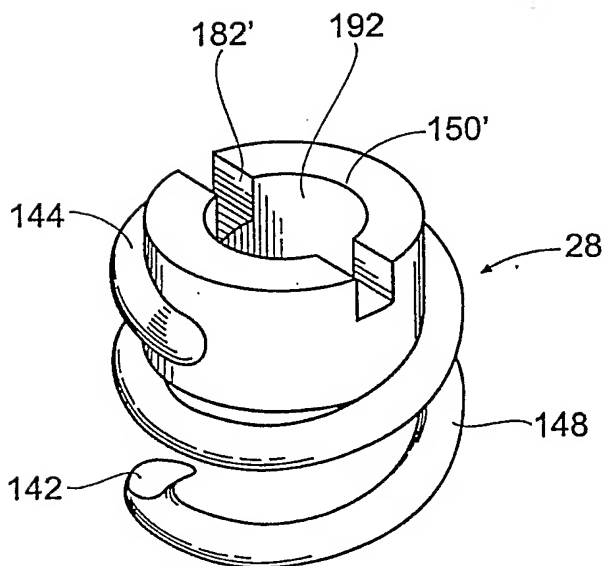


Fig. 28B

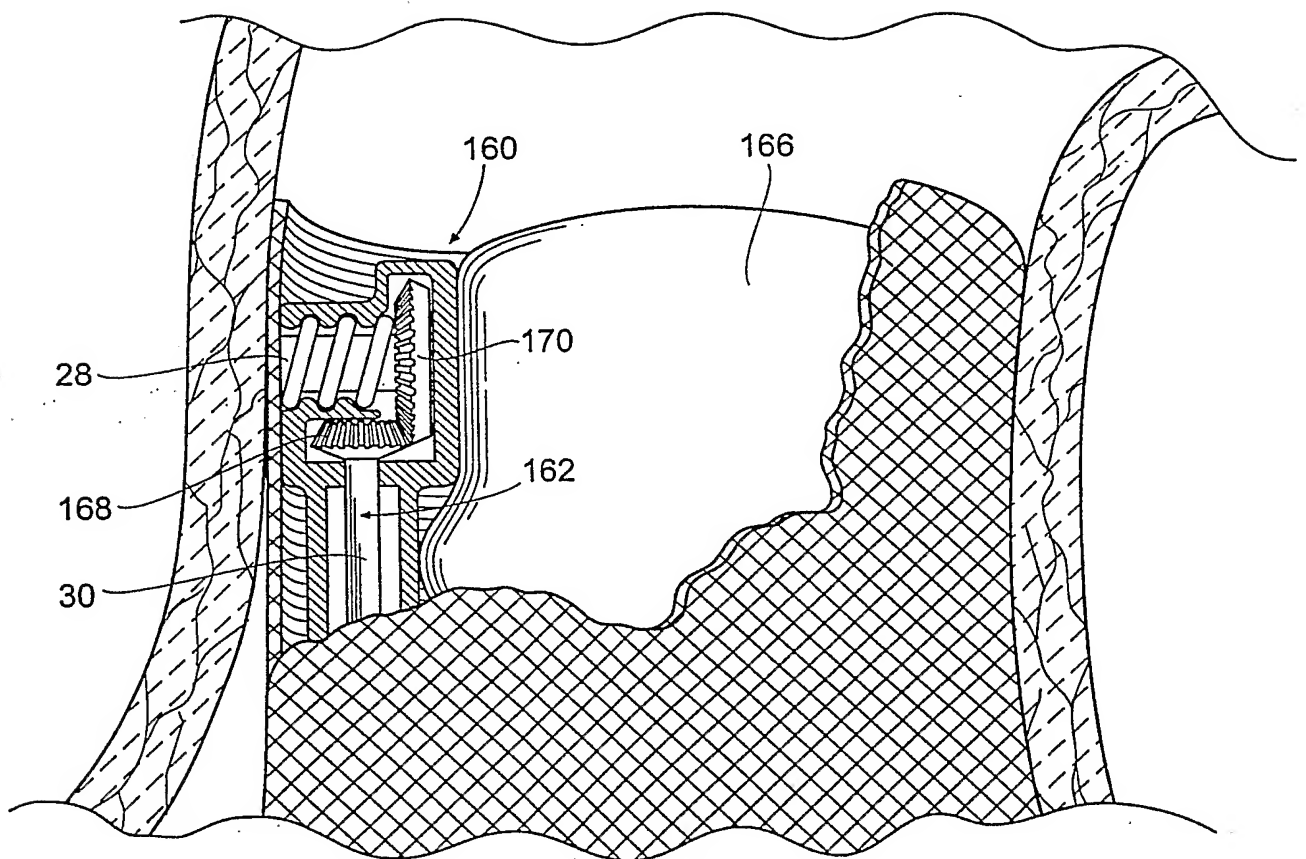


Fig. 29

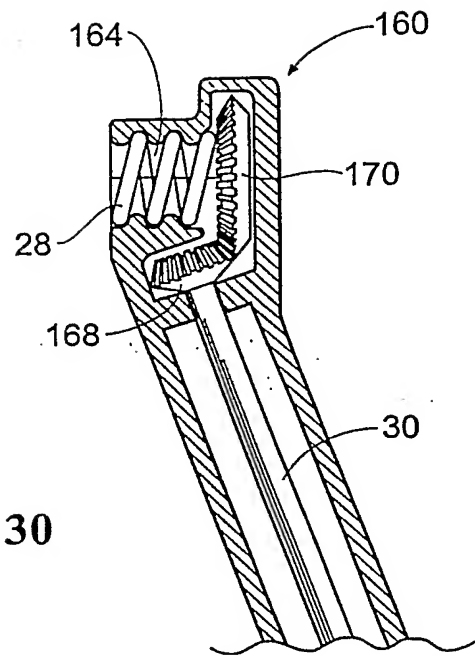


Fig. 30

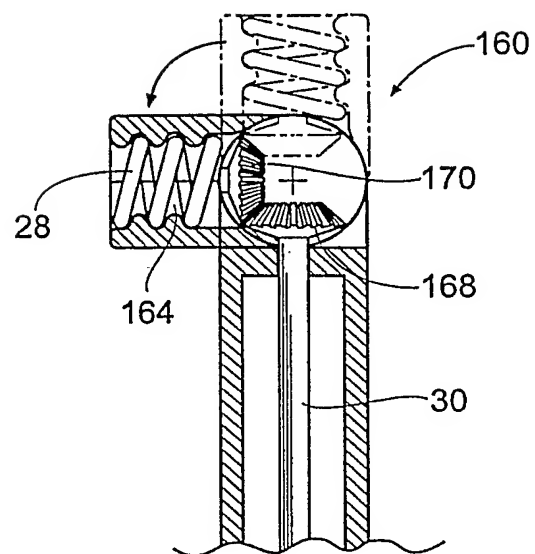


Fig. 31

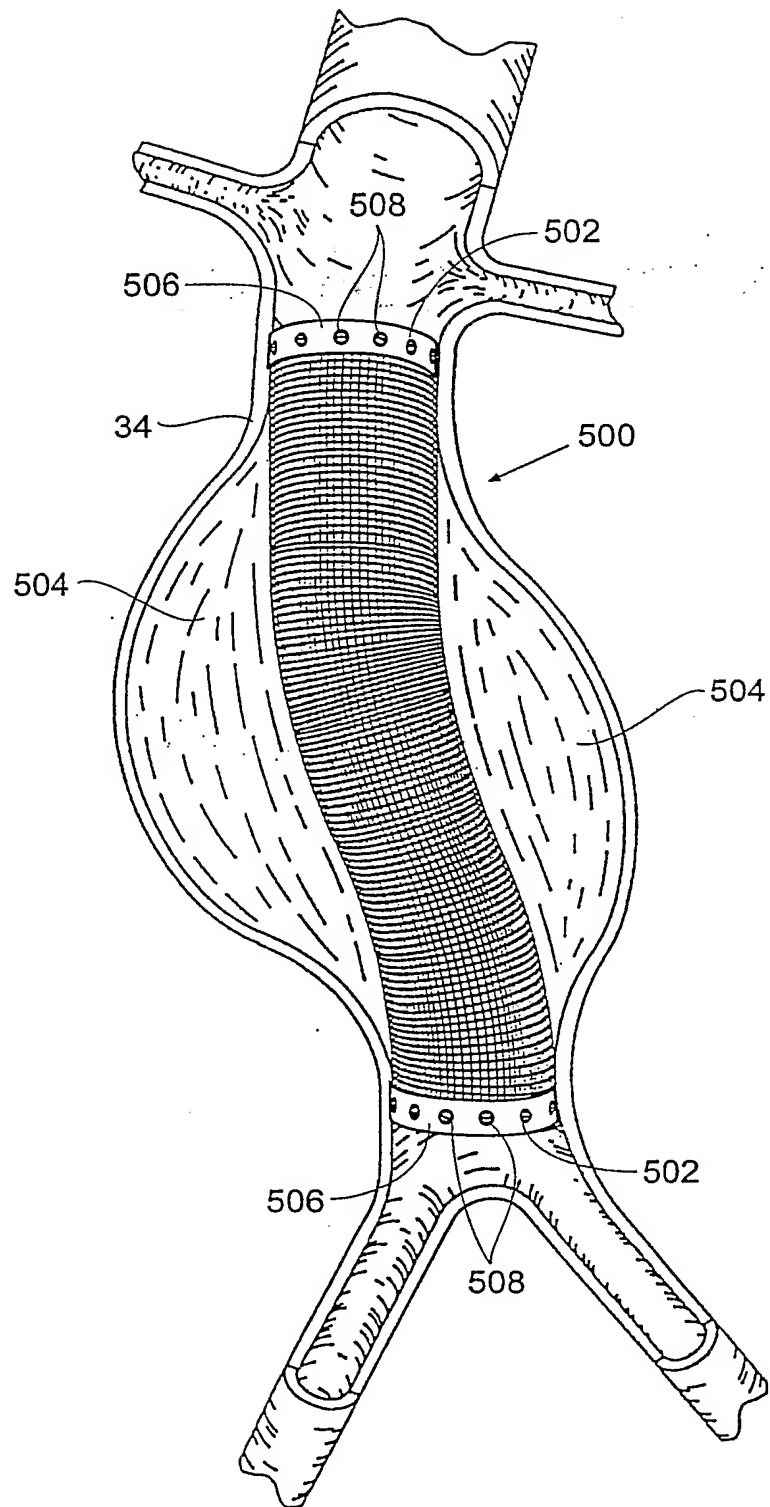
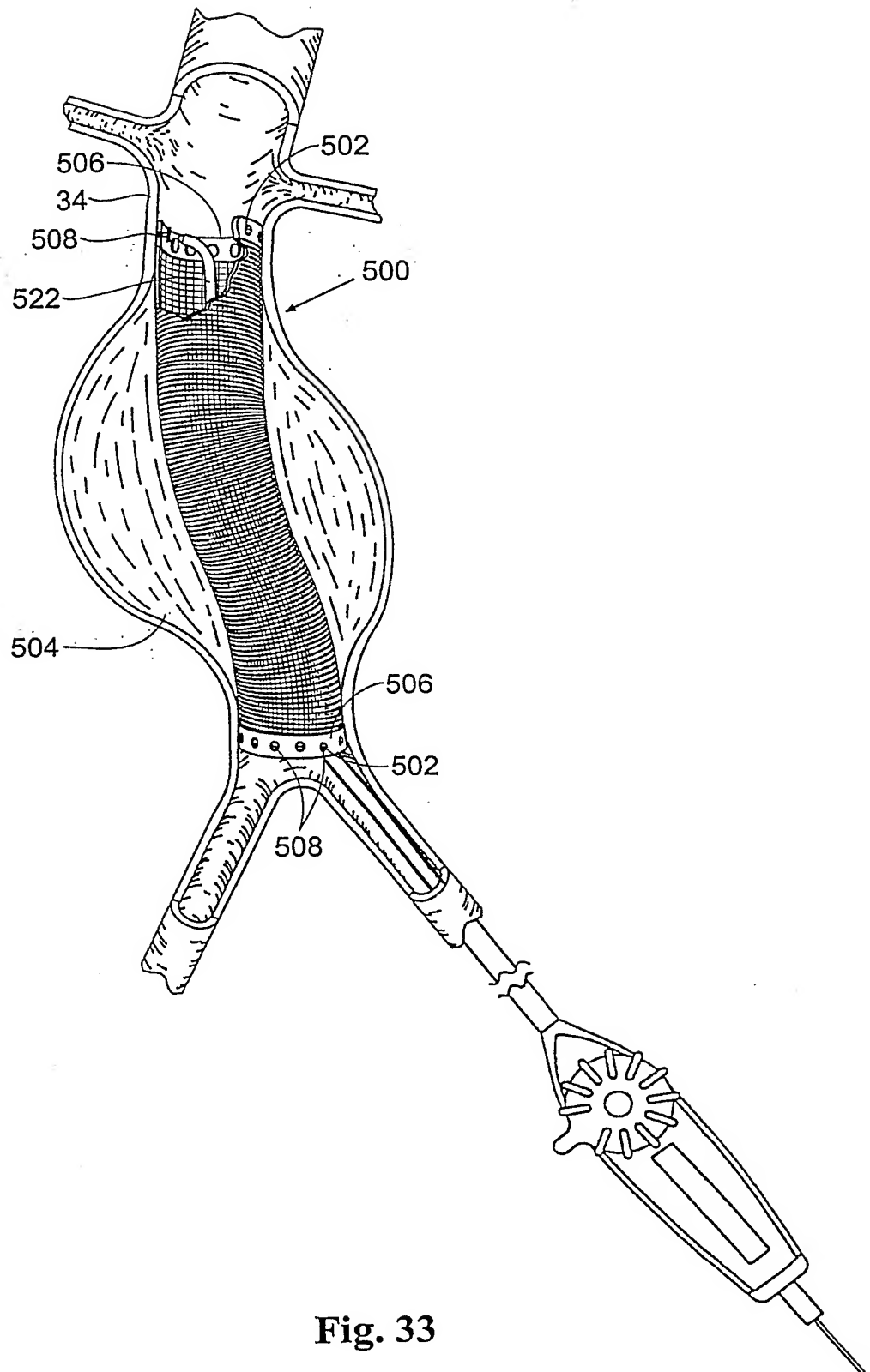


Fig. 32

**Fig. 33**

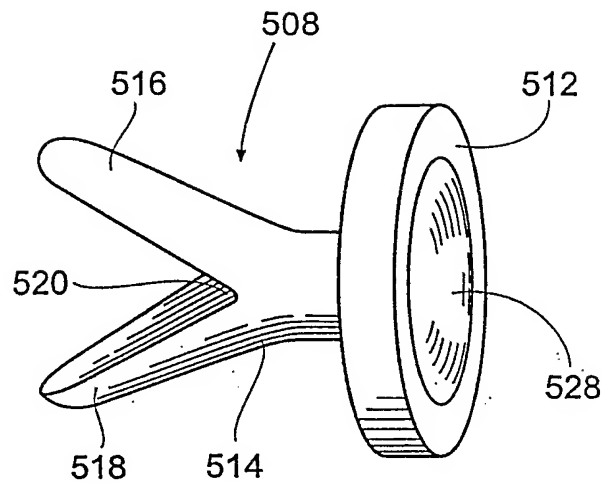


Fig. 34

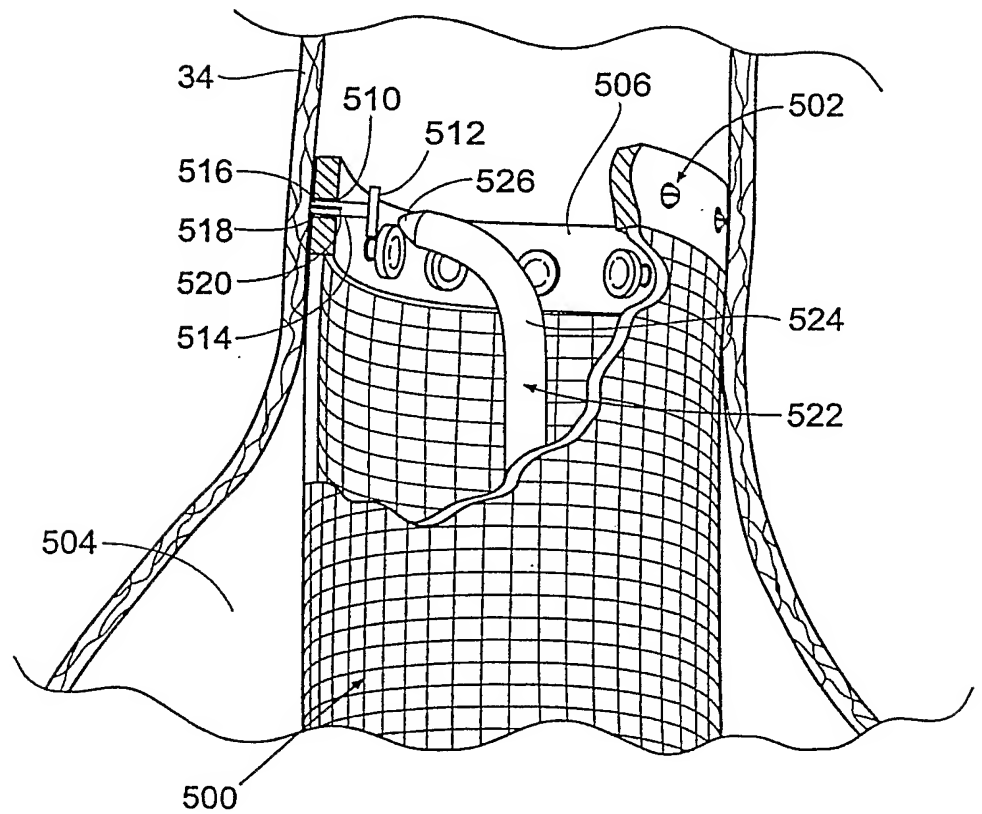
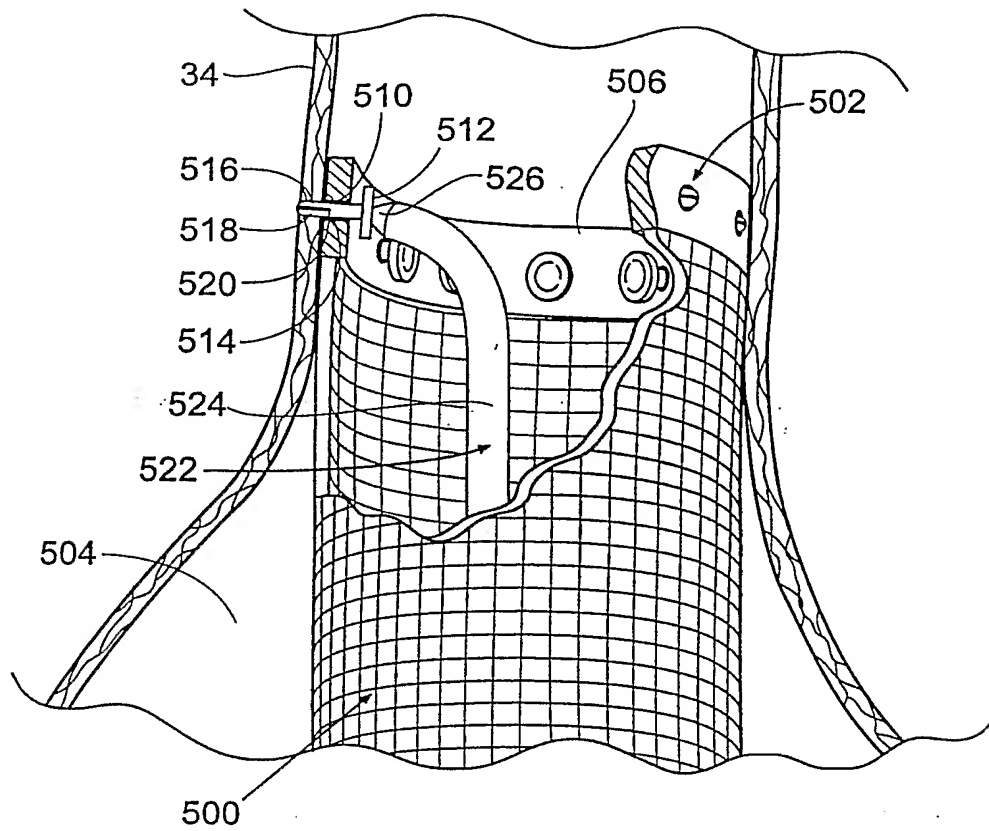
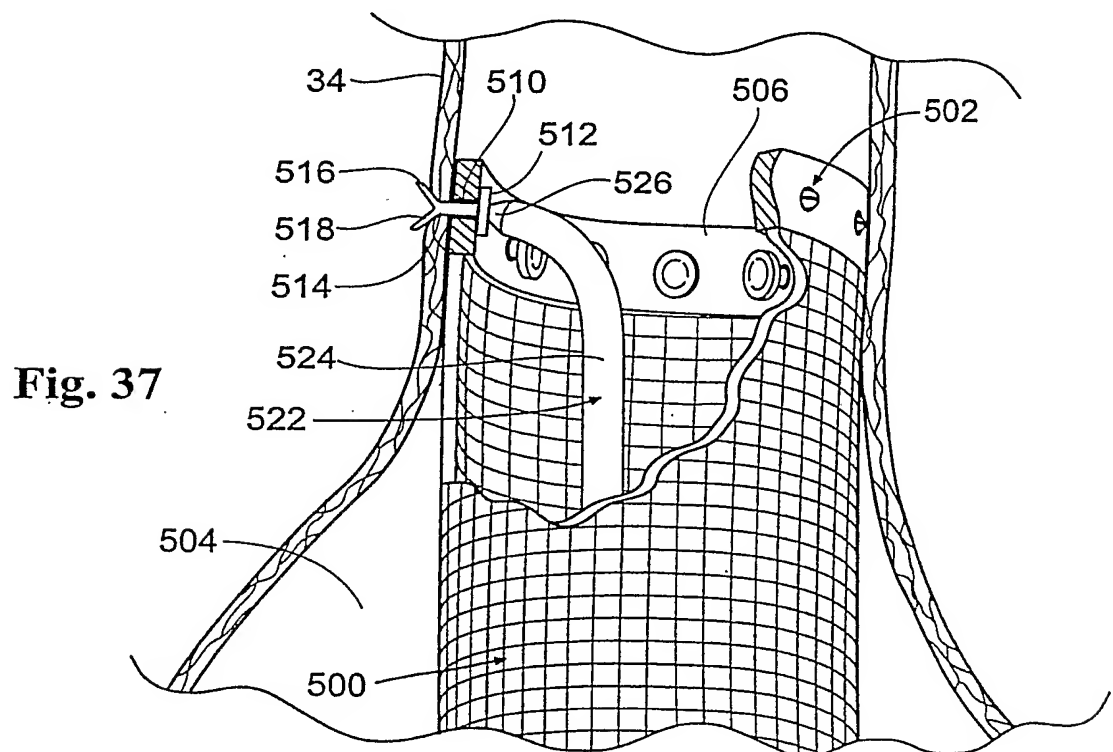


Fig. 35

**Fig. 36****Fig. 37**

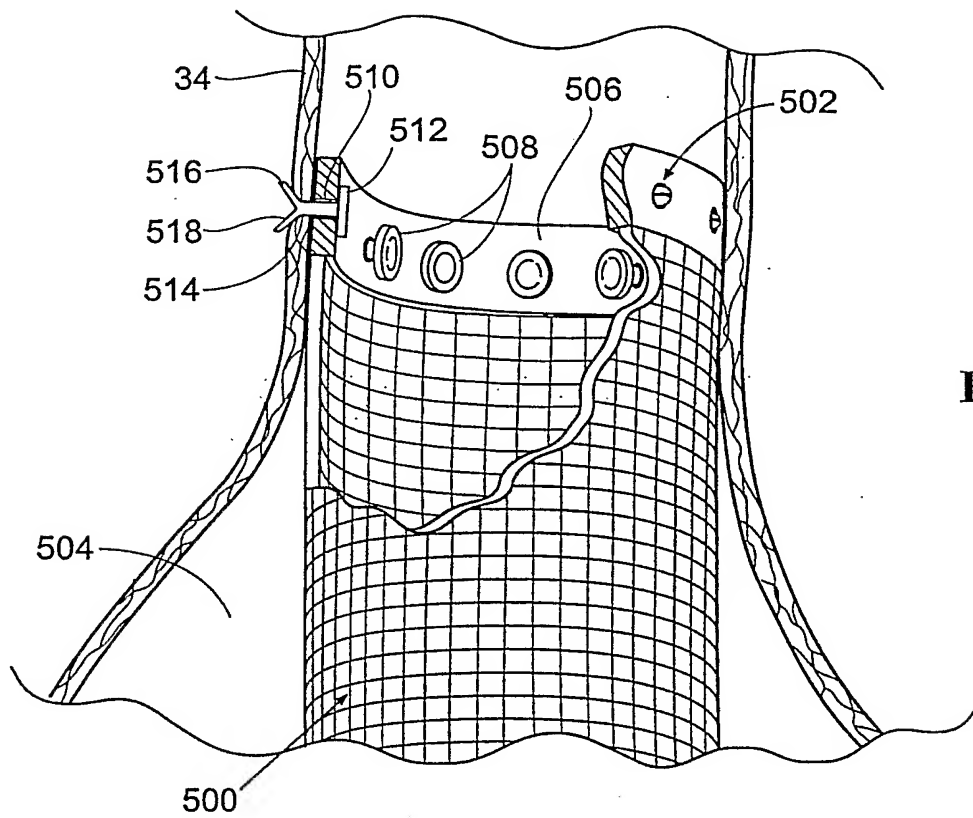


Fig. 38

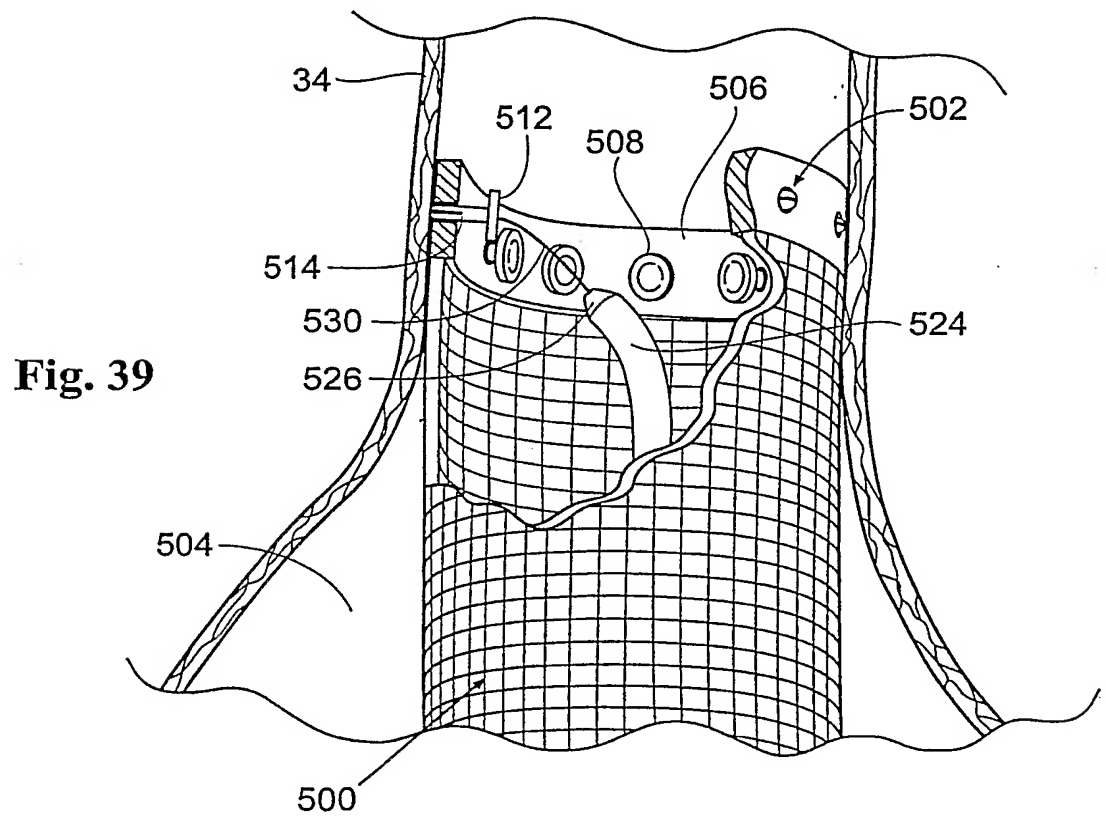
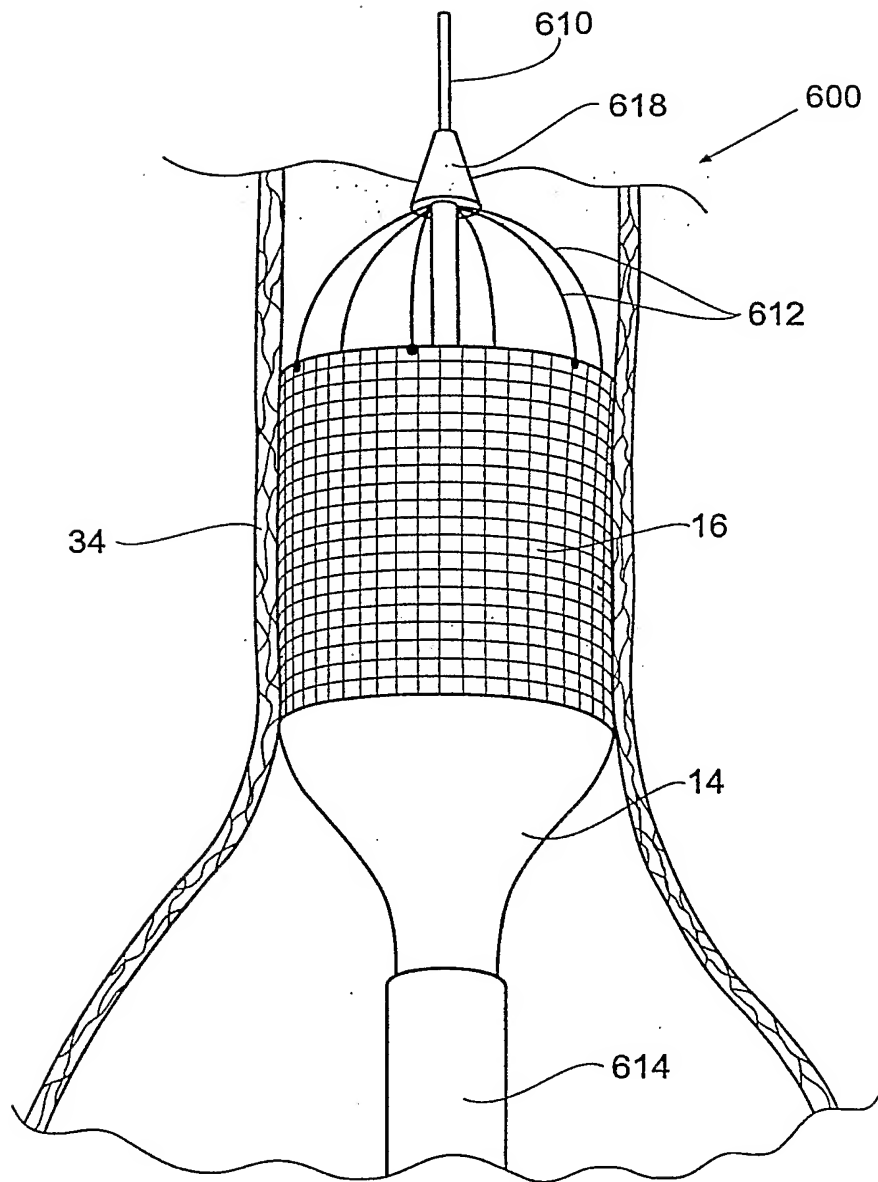
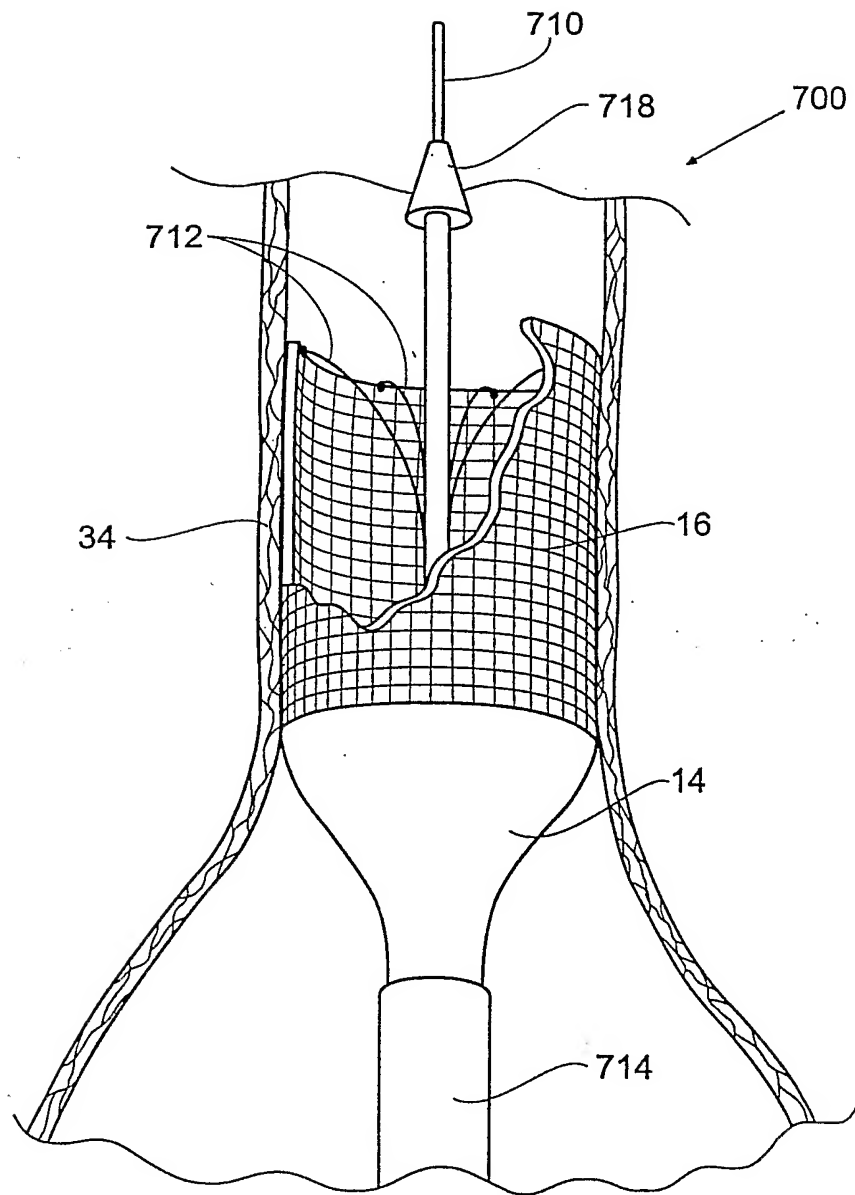
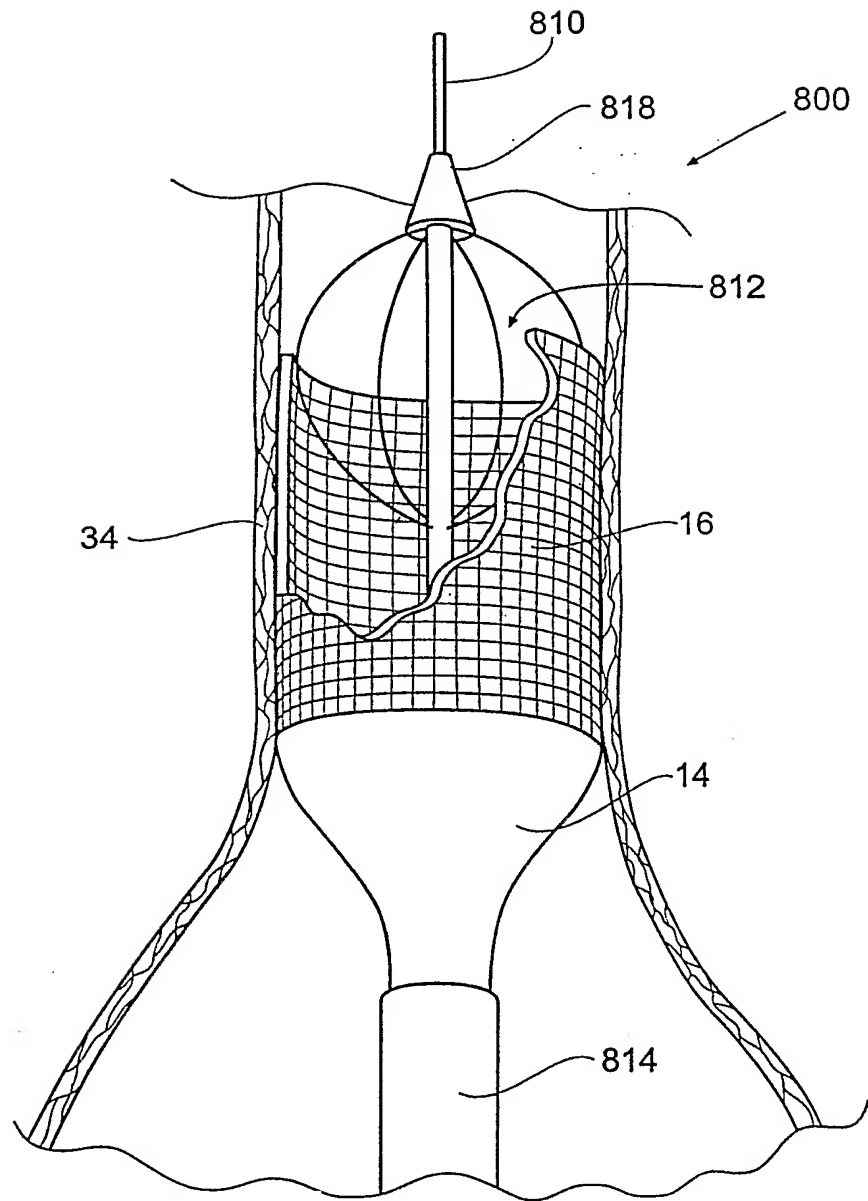
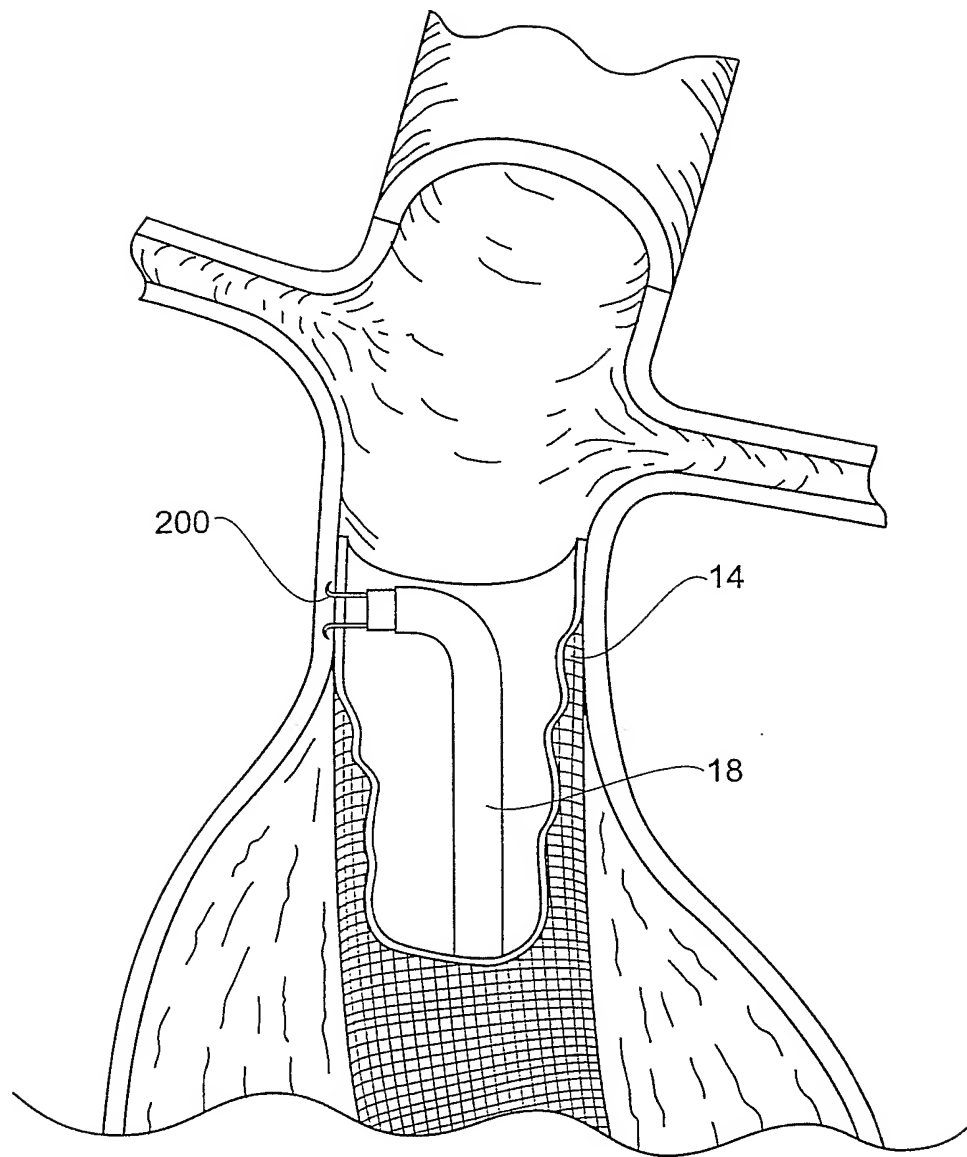


Fig. 39

**Fig. 40**

**Fig. 41**

**Fig. 42**

*Fig. 43*

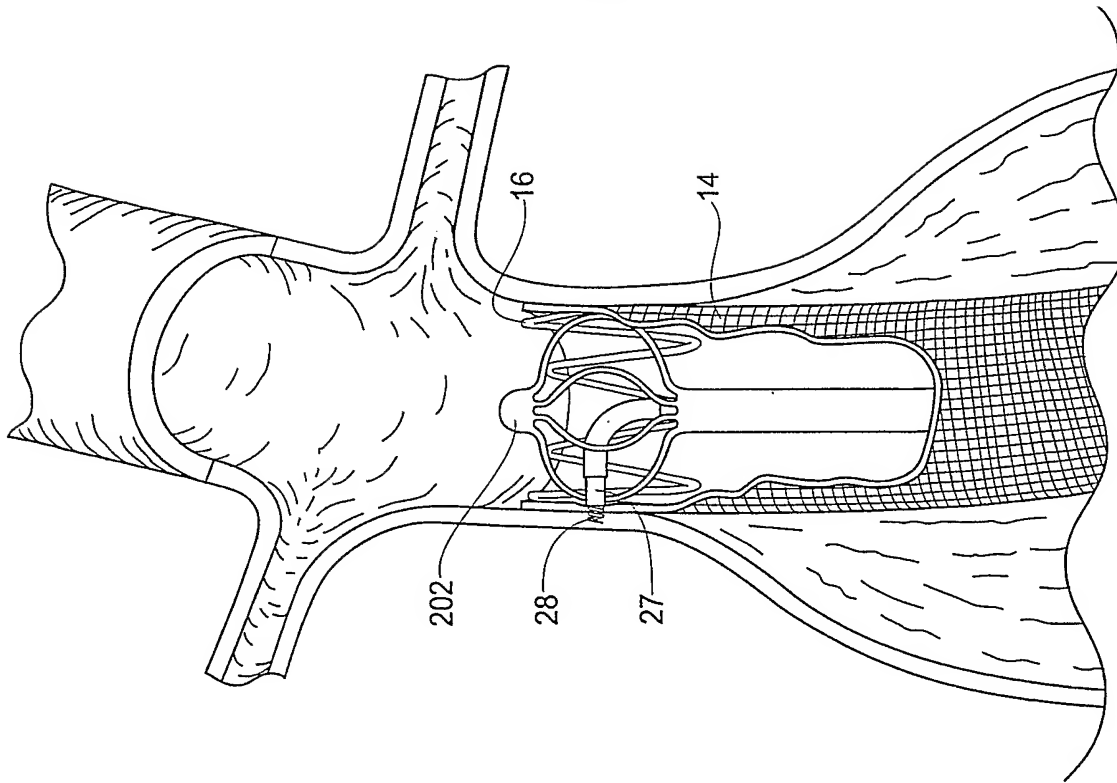


Fig. 44B

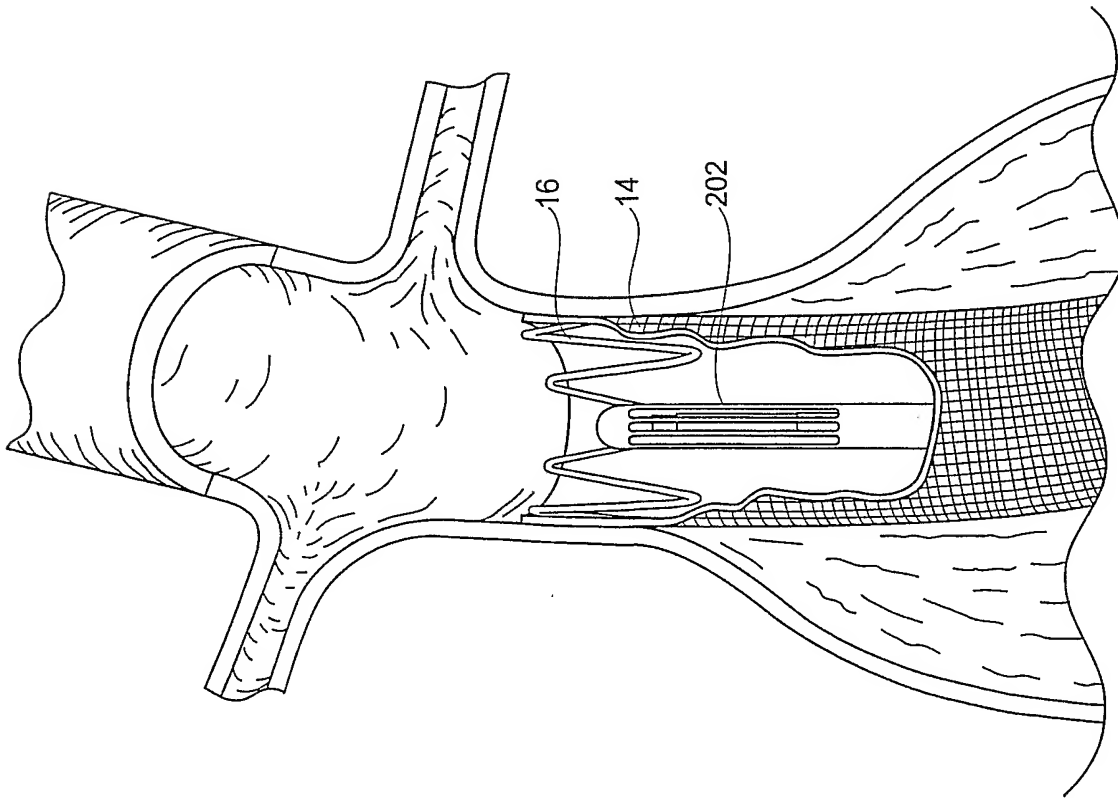
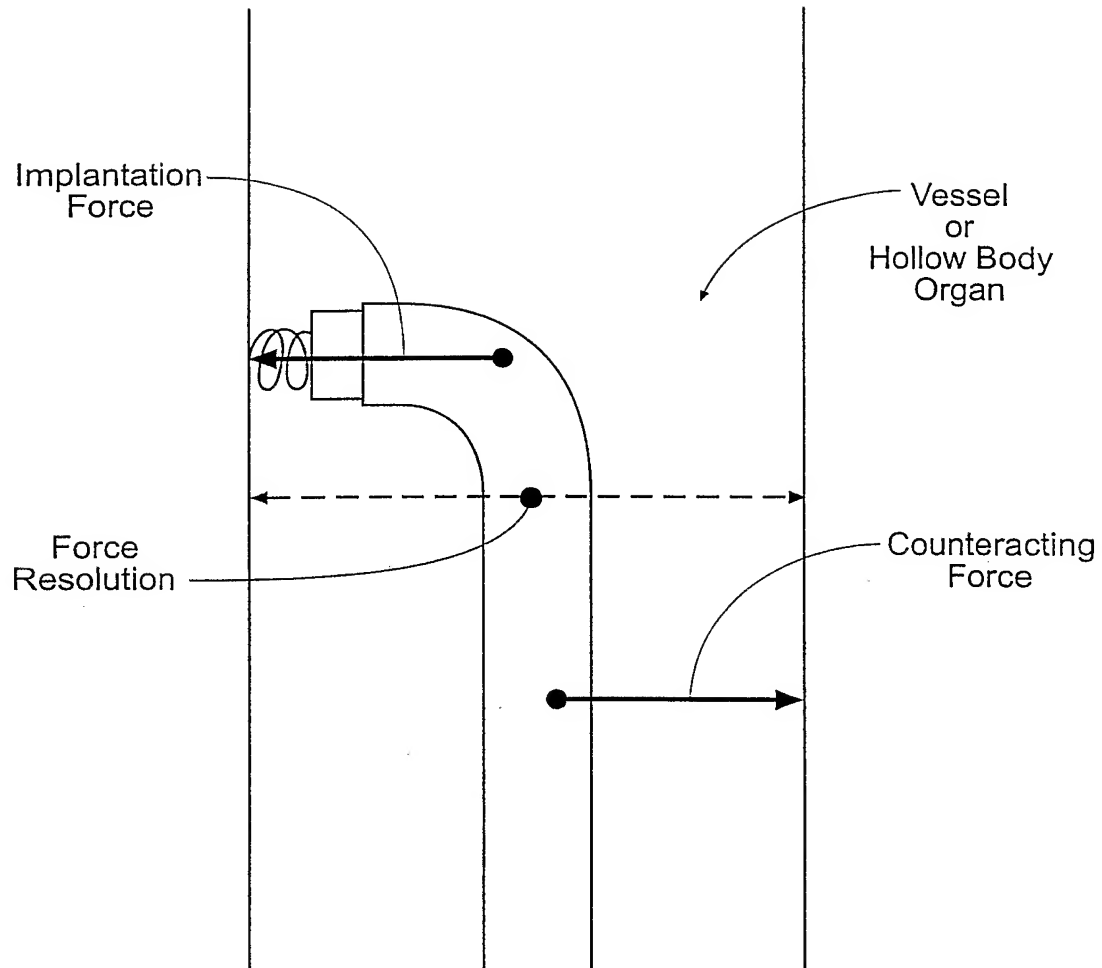


Fig. 44A

*Fig. 45*

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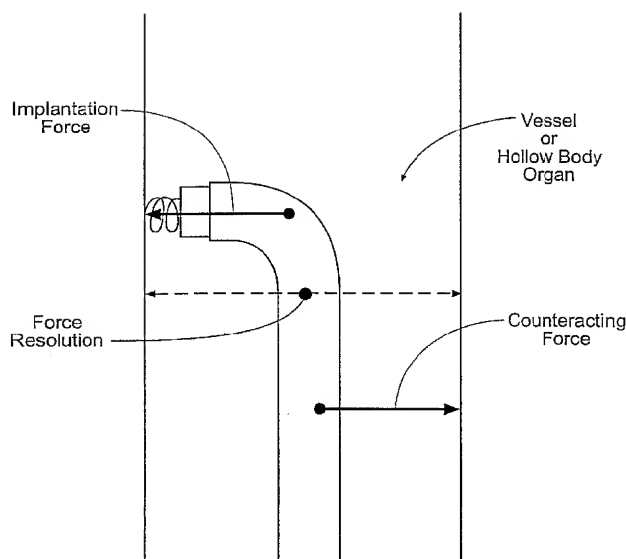
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(54) Title: CATHETER-BASED FASTENER IMPLANTATION APPARATUS AND METHODS WITH IMPLANTATION FORCE RESOLUTION



(57) Abstract: Apparatus and methods implant a fastener in a targeted body region, e.g., a hollow body cavity or an intraluminal space. The apparatus and methods deploy in targeted body region a fastener attachment assembly that carries an actuated member. The actuated member is selectively operable to generate an implantation force to implant a fastener into tissue within the targeted body region. The fastener can be implanted, e.g., to secure a prosthesis, e.g., an endovascular graft. The systems and apparatus apply a resolution force at or near the actuated member, thereby making possible a stable and dependable catheter-based fastening platform.



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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/29402

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
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Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)
EAST - endovascular near fastener

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 5,944,750 A (Tanner et al.) 31 August 1999, see figures 15A-38	1- 3,6,8,9,12,14,15,16,19, 21-24,27,29-32,35,37- 39 ----- 4,5,7,10,11,13,17,18,20 ,25,26,28,33,34,36
X	US 5,042,707 A (Taheri) 27 August 1991, see figs. 1, 3, 12	1,2,8,14,15,22,23,30,31 ,38,39

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ance Notes on Codes and Abbreviations" appearing at the begin-
ning of each regular issue of the PCT Gazette.

(54) Title: PROSTHESIS DELIVERY SYSTEMS AND METHODS

(57) Abstract: Apparatus and method deliver a prosthesis into a hollow body organ or blood vessel. The systems and methods make use of a catheter. A carrier on the distal end of the catheter is sized and configured to carry the prosthesis. A release mechanism and an enclosure mechanism on the distal end are operable to retain and enclose the prosthesis on the carrier. The release mechanism and the enclosure mechanism are also operable to selectively expose and release the prosthesis from the carrier for deployment in the hollow body organ or blood vessel.



WO 2005/044073 A2

PROSTHESIS DELIVERY SYSTEMS AND METHODS

Field of the Invention

The invention relates generally to the delivery of a prosthesis to a targeted site within the body, e.g., for the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel.

Background of the Invention

The weakening of a vessel wall from damage or disease can lead to vessel dilatation and the formation of an aneurysm. Left untreated, an aneurysm can grow in size and may eventually rupture.

For example, aneurysms of the aorta primarily occur in abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation. Aneurysms can also occur in the thoracic region between the aortic arch and renal arteries. The rupture of an aortic aneurysm results in massive hemorrhaging and has a high rate of mortality.

Open surgical replacement of a diseased or damaged section of vessel can eliminate the risk of vessel rupture. In this procedure, the diseased or damaged section of vessel is removed and a prosthetic prosthesis, made either in a straight or bifurcated configuration, is installed and then permanently attached and sealed to the ends of the native vessel by suture.

The prosthetic prosthesis for these procedures are usually unsupported woven tubes and are typically made from polyester, ePTFE or other suitable materials. The prosthesis are longitudinally unsupported so they can
5 accommodate changes in the morphology of the aneurysm and native vessel. However, these procedures require a large surgical incision and have a high rate of morbidity and mortality. In addition, many patients are unsuitable for this type of major surgery due to other co-morbidities.

10 Endovascular aneurysm repair has been introduced to overcome the problems associated with open surgical repair. The aneurysm is bridged with a vascular prosthesis, which is placed intraluminally. Typically these prosthetic prostheses for aortic aneurysms are
15 delivered collapsed on a catheter through the femoral artery. These prostheses are usually designed with a fabric material attached to a metallic scaffolding (stent) structure, which expands or is expanded to contact the internal diameter of the vessel. Unlike open
20 surgical aneurysm repair, intraluminally deployed prostheses are not sutured to the native vessel, but rely on either barbs extending from the stent, which penetrate into the native vessel during deployment, or the radial expansion force of the stent itself is utilized to hold
25 the prosthesis in position. These prosthesis attachment means do not provide the same level of attachment when compared to suture and can damage the native vessel upon deployment.

Summary of the Invention

30 One aspect of the invention provides apparatus and methods for delivering a prosthesis into a hollow body organ or blood vessel. The systems and methods include a catheter that is sized and configured for introduction into the hollow body organ or blood vessel.

35 A carrier on the distal end of the catheter is sized and

configured to carry the prosthesis. A release mechanism on the distal end is operable to retain the prosthesis on the carrier. The release mechanism is also operable to selectively release the prosthesis from the carrier for
5 deployment in the hollow body organ or blood vessel. An enclosure mechanism on the distal end is operable to enclose the prosthesis on the carrier. The enclosure mechanism is also operable to selectively expose the prosthesis on the carrier, to thereby enable the release
10 of the prosthesis from the carrier in response to selective operation of the release mechanism, which can occur separate from the operation of the enclosure mechanism or in conjunction with the enclosure mechanism. The systems and methods include at least one actuator,
15 which is coupled to the release mechanism and the enclosure mechanism, to selectively operate the release mechanism and the enclosure mechanism, either separately or in conjunction.

Other features and advantages of the invention
20 shall be apparent based upon the accompanying description, drawings, and claims.

Brief Description of the Drawings

The invention will be understood from the following detailed description of preferred embodiments,
25 taken in conjunction with the accompanying drawings, wherein:

Fig. 1A is a perspective view of a prosthesis delivery catheter embodies features of the invention.

Fig. 1B is an enlarged perspective view, with
30 portions broken away and in section, of the distal end of the prosthesis delivery catheter shown in Fig. 1A.

Fig. 2 is a perspective view of the prosthesis delivery catheter shown in Fig. 1A, being positioned within an abdominal aortic aneurysm.

35 Fig. 3 is a perspective view of a straight

endovascular prosthesis after deployment by the prosthesis delivery catheter shown in Fig. 1A.

Fig. 4 is a perspective view of a bifurcated endovascular prosthesis after deployment by the prosthesis delivery catheter shown in Fig. 1A.

Fig. 5A is an enlarged perspective view, with portions broken away and in section, of the inner assembly which is located in the distal end of the prosthesis delivery catheter shown in Fig. 1A.

Fig. 5B is an enlarged perspective view, with portions broken away and in section, of the inner assembly which is located in the distal end of the prosthesis delivery catheter shown in Fig. 5A, showing a prosthesis retained in a collapsed condition by restraining means prior to deployment.

Fig. 5C is an enlarged perspective view, with portions broken away and in section, of the inner assembly which is located in the distal end of the prosthesis delivery catheter shown in Fig. 5A, showing the prosthesis in an expanded condition after removal of the restraining means.

Fig. 6 is a side view, with portions broken away and in section, of the prosthesis delivery catheter shown in Fig. 1A, showing the catheter retaining a prosthesis in a collapsed condition prior to deployment, the outer sheath being shown in an advanced position over the prosthesis.

Fig. 7 is a side view, with portions broken away and in section, of the prosthesis delivery catheter shown in Fig. 6, showing the catheter retaining a prosthesis in a collapsed condition prior to deployment, the outer sheath being shown in a position withdrawn from the prosthesis.

Fig. 8 is a side view, with portions broken away and in section, of the prosthesis delivery catheter

shown in Fig. 7, showing the catheter retaining a prosthesis in a collapsed condition prior to deployment, with the pull wire still advanced to restrain radial expansion of the prosthesis.

5 Fig. 9 is a side view, with portions broken away and in section, of the prosthesis delivery catheter shown in Fig. 8, showing the prosthesis in a radially expanded condition after actuation of the pull wire to remove the restraining means.

10 Fig. 10 is a side view, with portions broken away and in section, of the prosthesis delivery catheter shown in Fig. 9, showing the withdrawal of the catheter from the prosthesis after its deployment.

15 Fig. 11A is a simplified side view of the distal end of the prosthesis delivery catheter shown in Fig. 5B, with the outer sheath removed, showing the releasing means retaining the prosthesis in a restrained condition.

20 Fig. 11B is an end section view of the distal end of the prosthesis delivery catheter shown in Fig. 11A, taken generally along line 11B-11B in Fig. 11A.

25 Fig. 11C is a simplified side view of the distal end of the prosthesis delivery catheter shown in Fig. 5B, with the outer sheath removed, showing an alternative embodiment of a restraining means for maintaining the releasing means in a desired orientation while retaining the prosthesis in a restrained condition.

30 Figs. 12A and 12B are simplified side views of the distal end of the prosthesis delivery catheter shown in Fig. 5B, with the outer sheath removed, showing other alternative embodiments of a restraining means for maintaining the releasing means in a desired orientation while retaining the prosthesis in a restrained condition, without reliance upon the catheter tip component.

35 Figs. 13A and 13B are simplified side views of

the distal end of the prosthesis delivery catheter shown in Fig. 5B, with the outer sheath removed, showing other alternative embodiments of a restraining means for maintaining the releasing means in a desired orientation while retaining the prosthesis in a restrained condition, without reliance upon a tubular sleeve carried by the central shaft.

Figs. 14A and 14B are simplified side views of the distal end of the prosthesis delivery catheter shown in Fig. 5B, with the outer sheath removed, showing other alternative embodiments of a releasing means with a cutting element for selectively releasing the prosthesis for use, together with an associated restraining means for maintaining the releasing means in a desired orientation for operation.

Figs. 15A and 15B are simplified side views of the distal end of the prosthesis delivery catheter shown in Fig. 5B, with the outer sheath removed, showing other alternative embodiments of a releasing means with a wedge element for selectively releasing the prosthesis for use, together with an associated restraining means for maintaining the releasing means in a desired orientation for operation.

Detailed Description of the Invention

I. PROSTHESIS DELIVERY CATHETER

Figs. 1A and 1B show a prosthesis delivery catheter 10. The purpose of the catheter 10 is to (i) contain and/or restrain a prosthesis 14 prior to its deployment (see Fig. 1B), (ii) deliver the prosthesis 14 through the vasculature to a desired location within the body, e.g., a hollow body organ or a blood vessel (see Fig. 2), and (iii) controllably deploy the prosthesis 14 in the desired location (see Fig. 3).

In the illustrated arrangement (see Fig. 3),

the prosthesis 14 takes the form of an endovascular, self-expanding stent prosthesis. In this respect, the prosthesis or prostheses 14 may have a wide variety of conventional configurations. It can typically comprise a
5 fabric or some other blood semi-impermeable flexible barrier which is supported by a structure formed by stents 48. The stent structure can have any conventional stent configuration, such as zigzag, serpentine, expanding diamond, or combinations thereof. The stent
10 structure may extend the entire length of the prosthesis, and in some instances can be longer than the fabric components of the prosthesis. Alternatively, the stent structure can cover only a small portion of the prosthesis, e.g., being present at the ends. The stent
15 structure may have three or more ends when it is configured to treat bifurcated vascular regions, such as the treatment of abdominal aortic aneurysms, when the stent prosthesis extends into the iliac arteries. In certain instances, the stent structures can be spaced
20 apart along the entire length, or at least a major portion of the entire length, of the stent-prosthesis, where individual stent structures are not connected to each other directly, but rather connected to the fabric or other flexible component of the prosthesis. Still, it
25 is contemplated that the stent structures could be attached to one another at discrete locations, e.g., in the proximal neck region. Such stent structures could comprise individual stents that are connected together when incorporated into the prosthesis, or stents that are
30 manufactured in a joined condition prior to incorporation into the prosthesis.

The stents 48 may be elastic, e.g., comprised of a shape memory alloy elastic stainless steel, or the like. For elastic, expanding typically comprises
35 releasing the stent structure from a constraint to permit

the stent structure to self-expand at the implantation site. As will be described in greater detail, the catheter 10 places a sheath over the stent structure, in combination with releasable restraining means coupled to
5 the stent structure, to maintain the stent structure in a radially reduced configuration during passage into the body. In this arrangement, self-expansion of the stent structure is achieved by pulling back on the sheath and release of the restraining means, to permit the stent
10 structure to assume its larger diameter configuration.

Alternatively, the stent structure may be formed from a malleable material, such as malleable stainless steel or other metals. Expansion may then comprise applying a radially expansive force within the
15 structure to cause expansion, e.g., inflating a delivery catheter within the stent structure in order to affect the expansion. In this arrangement, the positioning and deployment of the endoprosthesis can be accomplished by the use of an expansion means either separate or
20 incorporated into the deployment catheter. This will allow the endoprosthesis to be positioned within the vessel and partially deployed while checking relative position within the vessel. The expansion can be accomplished either via a balloon or mechanical expansion
25 device. Additionally, this expansion stabilizes the position of the endoprosthesis within the artery by resisting the force of blood on the endoprosthesis until the endoprosthesis can be fully deployed. Still, alternatively, the stent structure may comprise a
30 combination of a self-expanding stent and a malleable stent structure.

In the illustrated embodiment (see Fig. 2), the catheter 10 is shown it is being positioned over a guidewire 12 in a body lumen. The catheter 10 carries the
35 prosthesis 14 in a radially reduced configuration to a

targeted site. At the targeted site, the catheter 10 releases the radially reduced prosthesis 14, which expands radially (see Fig. 3). After partial or complete expansion or deployment of the prosthesis 14, one or more
5 fasteners are desirably introduced by a fastener attachment assembly to anchor the prosthesis 14 in place. Further details of the fastener attachment assembly can be found in United States Patent Application Serial No. 10/307,226, filed November 29, 2002, which is
10 incorporated herein by reference.

The prosthesis 14 can be sized and configured to be either straight or bifurcated form. Fig. 3 depicts a completely deployed straight prosthesis 14. Fig. 4 depicts a completely deployed bifurcated prosthesis.

15 For the purposes of illustration, Fig. 2 shows the targeted site as being within an abdominal aortic aneurysm. Of course, the targeted site can be elsewhere in the body.

As shown in Figs. 1A and 1B, the catheter 10
20 comprises an inner assembly 16, an outer sheath 18, and a handle assembly 20. These components will now be individually described in greater detail.

A. The Inner Assembly

In the illustrated embodiment (see Fig. 5A),
25 the inner assembly 16 comprises a central shaft 22, which functions as a carrier for the prosthesis. The inner assembly also includes a catheter tip component 24, a releasing means or mechanism 28 for retaining at least a portion of the prosthesis 14 in a radially compressed
30 condition prior to deployment, a retaining means or mechanism 26 for maintaining the releasing means 28 in a desired relationship with the central shaft 22 during use, and a spacer 30.

In the embodiment shown in Fig. 5A, the
35 central shaft 22, the retaining means 26, the releasing

means 28, and the spacer 30 are located within the confines of the outer sheath 18. In this respect, the outer sheath 18 functions as an enclosure for the prosthesis on the carrier. In this arrangement, the catheter tip component 24 is attached the distal end of the central shaft 22, and the distal end of the outer sheath 18 terminates adjacent the catheter tip component 24. Thus, the catheter tip component 24 extends outward beyond the outer sheath 18. The central shaft 22, the releasing means 28, and the outer sheath 18 connect to the handle assembly 20 at the proximal end of the catheter 10 (see Fig. 1A). In use (see Fig. 5B), the prosthesis 14 is contained in a cavity 32 defined between the central shaft 22 and the outer sheath 18 in the distal section of the catheter 10 (this arrangement is also shown in Fig. 1B).

The central shaft 22 extends from the handle assembly 20 (see Fig. 1A) to the catheter tip component 24. The central shaft 22 may be made, e.g., from stainless steel or other suitable medical materials including other metals or polymers. The central shaft 22 desirably has at least one lumen 36 (see Fig. 5A), with an inner diameter between .010 and .120 inches, preferably between .03 and .06 inches and most preferably between .04 and .05 inches.

As described, the central lumen 36 allows for the insertion of a guide wire 12 up to 0.038" diameter. The catheter tip component 24 also desirably has at least one lumen 38 (see Fig. 5A) configured to align with at least one lumen within the central shaft 22. This lumen 38 allows for the insertion of a guide wire 12 through the central shaft 22 and through the catheter tip component 24 (see Fig. 2). Typically this lumen will have an inner diameter between 0.010 and .120 inches, preferably between .03 and .06 inches and most preferably between

.04 and .05 inches.

Preferably, the catheter tip component 24 is flexible and has a long, tapered distal end and a shorter, tapered proximal end. The maximum diameter of the catheter tip component 24 is approximately the same as the outside diameter of the distal end of the outer sheath 18. The distal end of the catheter tip component 24 provides a smooth tapered transition from the lumen 38 containing the guide wire 12 to the distal edge of the outer sheath 18. This feature aids in catheter insertion and navigation through tortuous anatomy over the guide wire 12. The tapered section on the proximal end of the catheter tip component 24 prevents the catheter tip component 24 from inadvertently engaging the prosthesis 14, portions of the surrounding anatomy, or an introducer sheath or the like during removal of the catheter 10 from the body.

Still referring to Fig. 5A, the retaining means 26 holds the releasing means 28 in a desired, close relationship with the central shaft 22. The retaining means 26 orients the releasing means 28 along the axis of the central shaft 22 and allows the releasing means 28 longitudinal movement in this axis. In the embodiment shown in Figs. 5A, 5B, and 5C, the retaining means 26 includes a small hole or recess 40 in the proximal end of the catheter tip component 24 and a tube 56 having a diameter sufficiently large to accommodate both the central shaft 22 and the releasing means 28. In the embodiment shown in Figs. 5A, 5B, and 5C, the tube 56 of the retaining means 26 is located over the central shaft 22 in alignment with and adjacent to the recess 40 on the catheter tip component 24. The tube 56 is attached to the central shaft 22 in a manner in that retains a crescent shape lumen 42 between the tube 56 and the central shaft 22. The releasing means 28 extends through this lumen 42

and into the recess 40.

Returning to Fig. 5A, the spacer 30 provides support for the outer sheath 18 and, by occupying space within the outer sheath 18, reduces the amount of air entrapped within the catheter 10. The distal end of the spacer 30 desirably terminates adjacent the proximal end of the prosthesis 14 (as Fig. 5B shows). In this arrangement (see Fig. 5B), the cavity 32 containing the prosthesis 14 extends from the proximal end of the catheter tip component 24 to the distal end of the spacer 30. As Fig. 5A shows, the spacer 30 is positioned over the central shaft 22 and releasing means 28 and the proximal end of the spacer 30 is connected to the handle assembly 20. Typically, the spacer 30 can have an outer diameter slightly less than the inner diameter of the outer sheath 18. The spacer 30 can comprise a single lumen or an array of multiple lumens for passage of the various components within the spacer 30.

The releasing means 28 holds the prosthesis 14 in a desired configuration prior to deployment (see Fig. 5B) and selectively releases the prosthesis 14 for deployment (see Fig. 5C). In the illustrated embodiment, the proximal end of the releasing means 28 is connected to an actuator or control button or knob 46 in the handle assembly 20 (see Fig. 1A). As Fig. 5B shows, the releasing means 28 extends along the outside of the central shaft 22, through the inside of the spacer 30, and continues distally through the inside of the prosthesis 14. The releasing means 28 passes through the prosthesis 14 and the retaining means 26.

As Fig. 5B best shows, the prosthesis 14 is retained by the releasing means 28 along the central shaft 22 in the cavity 32, which extends between the proximal end of the catheter tip component 24 and the distal end of the spacer 30. In the illustrated

embodiment, the releasing means 28 includes a wire 58 that extends along the central shaft 22. The distal end of the wire 58 passes through the crescent shape lumen 42 of the retaining means 26, and is ultimately captured in the hole or recess 40 of the retaining means 26 in the proximal end of the catheter tip component 24. The distal end of the wire 58 is thereby kept in a desired relationship along the central shaft 22. The proximal end of the wire 58 is coupled to the control button 46, such that fore and aft movement of the button 46 advances the wire 58, respectively, distally and proximally.

As Fig. 5B shows (and which is further shown in more schematic form in Figs. 11A, 11B, and 11C), the retaining means 28 includes sutures 44 and/or equivalent structures, which are attached to one or more stents 48 on the prosthesis 14. The sutures 44 are, in turn, looped around the wire 58 of the releasing means 28, when the wire 58 is in its distal-most position, as Fig. 5B shows. Proximal advancement of the wire 58 (using the control button 46) withdraws the wire 58 from the suture loops 44, as Fig. 5C shows.

In the illustrated embodiment (see Fig. 5B as well as Figs. 11A, 11B, and 11C), the suture loops 44 are attached to one or more stents 48 at the distal end of the prosthesis 14. It should be appreciated, however, that suture loops 44 could be attached to stents 44 elsewhere in the prosthesis 14, and/or the other components of the prosthesis 14 as well.

The suture loops 44 and wire 56 of the embodiment of the releasing means 28 just described retain the prosthesis 14 to the central shaft (see Fig. 5B). The suture loops 44 and the wire 56 keep the prosthesis 14 from moving proximally as the outer sheath 18 is retracted. The releasing means 28 also keeps the stents 48 that are coupled to the suture loops 44 in a

radially compressed condition as the outer sheath 18 is removed. The suture loops 44 and wire 56 prevent the distal end of the prosthesis 14 from self-expanding until the releasing means 28 has been withdrawn. In the
5 illustrated embodiment, the withdrawal of the releasing means 28 is accomplished by operating the control button 46 to move the wire 58 proximally, withdrawing the wire 58 from the hole or recess 40 and away from the suture loops 44. Once the releasing means 28 is withdrawn, the
10 restrained components of the prosthesis 14 are freed to self expand, as Fig. 5C shows.

As illustrated and described, the releasing means 28 is coupled to one restrained component of the prosthesis 14. It should be appreciated, however, that
15 the releasing means 28 can be coupled to the prosthesis 14 at two or more restrained regions, so that withdrawal of the releasing means 28 frees the prosthesis at two or more restrained regions. It should also be appreciated that the releasing means 28 can comprise more than a
20 single releasing element. For example, multiple, individual releasing wires 58 could be coupled to the prosthesis 14 at different regions, so that release of separate regions of the prosthesis 14 can be individually controlled.

25 B. The Outer Sheath

The outer sheath 18 also serves to restrain the stents 48 on the prosthesis 14 from expanding and allows for a control deployment of the prosthesis 14 within the body. In the illustrated arrangement, the
30 outer sheath 18 is connected to an actuator or a collar or knob 50 on the handle assembly 20. As Fig. 5A shows, the outer sheath 18 extends distally over the spacer 30 and prosthesis 14 and terminates adjacent the proximal and of the catheter tip component 24. Typically, the
35 outer sheath 18 can be made of a polymer tube and be free

of structural reinforcement.

In the illustrated embodiment (see Fig. 5A), the outer sheath 18 is tapered due to the difference in outer diameters of the catheter tip component and the spacer 30. The larger diameter of the outer sheath 18 is intended to contain the main body of the prosthesis 14 and the smaller diameter would contain the leg portion or portions of the prosthesis 14, if present (as in the embodiment shown in Fig. 4). The smaller diameter continues proximally to the handle assembly 20. This tapered feature of the outer sheath 18 also allows for better blood circulation passed the catheter.

C. Handle Assembly

The handle assembly 20 provides the operator with longitudinal and rotational control of the catheter 10 within the body and provides access to the actuator or control means for deploying the prosthesis 14.

In the illustrated embodiment, the handle assembly 20 comprises a handle body 52 and the sliding knob or collar 50 which is connected to the proximal and the of the outer sheath 18, and the knob or button 46 which is attached to proximal end of the releasing means 28. In the illustrated embodiment, the central shaft 22 is captured within the handle and has a guide wire receiving luer 34 connected to its proximal end, which is located at the proximal end of the handle assembly 20. This design prevents the position of the prosthesis 14 from moving relative to the handle body 52 while the outer sheath 18 is retracted.

To withdraw the outer sheath 18 from the prosthesis 14 (see Figs. 6 and 7), the sliding knob 50 is moved proximally until the distal end of the outer sheath 18 is free of the prosthesis 14 (see Fig. 8). The portion or portions of the prosthesis 14 that are not coupled to the releasing means 28 (which, in the illustrated

embodiment comprise the proximal region of the prosthesis 14) are free to self-expand, as Fig. 8 shows. However, the portions of the prosthesis 14 that are coupled to the releasing means 58 (which, in the illustrated embodiment
5 comprise the distal region of the prosthesis 14) are still restrained from self-expansion, despite withdrawal of the outer sheath 18, as Fig. 8 also shows. The stent structure of the prosthesis 14 is thereby kept restrained closely against the central shaft tube 22 while the outer
10 sheath 18 is retracted. The retaining means 26 prevents the prosthesis 14 from moving relative to the central tube 22 during retraction of the outer sheath 18, which potentially minimizes blood flow through the prosthesis 14 during the deployment process. Furthermore, as
15 described, the prosthesis 14 is not "pushed out" of the catheter. The prosthesis 14 therefore need not have longitudinal stiffness or a stent structure with a "spine".

To withdraw the releasing means 28 (see Figs. 8 and 9), the sliding button 46 is moved proximally until
20 the distal end of the releasing means 28 is withdrawn from the restraining means 26. The prosthesis is thereby free to fully self-expand, as Fig. 9 and Fig. 5C show. As described, the prosthesis 14 is not released immediately
25 from distal end to proximal end as the sheath 18 is withdrawn. As the outer sheath 18 is retracted, the prosthesis 14 is pulled in tension, which "stretches" the prosthesis to its proper length and stent spacing. The distal stent or stents 48 are released in a secondary
30 operation, which follows the withdrawal of the outer sheath 18 (as shown in Figs. 5C, 8, and 9). Final placement of distal end of the prosthesis 14 can therefore comprise a final step in the deployment process.

35 It should be appreciated that the knob 50 can

comprise a separate component that is not part of the handle assembly 20, i.e., on the outer sheath 18.

II. . USE OF THE PROSTHESIS DELIVERY CATHETER

During use, the catheter 10 is navigated over
5 the guide wire 12 to the desired location within the body
(as Fig. 2 shows). In the illustrated embodiment,
deployment of the prosthesis 14 is achieved in a two step
process. First, by pulling the knob or collar 50 on the
handle assembly 20 proximally, the outer sheath 18 is
10 retracted and exposes the prosthesis 14 (as Figs. 6 and 7
show). The unrestrained portion or portions of the
prosthesis 14 self-expand, as Fig. 8 show. As Figs. 6 and
7 show, during retraction of the outer sheath 18, the
prosthesis 14 maintains its position relative to the
15 central shaft 22 due to the releasing means 28 connected
to the prosthesis 44.

In the second step of the deployment process,
following the withdrawal of the outer sheath 18, the
control button or knob 46 on the handle assembly 20 is
20 moved proximally (see Figs. 8 and 9). This causes the
distal end of the releasing means 28 to be withdrawn and
allows the restrained stent or stents 44, and the
prosthesis 14 as a whole, to self-expand radially (as
Figs. 5C and 9 show). The prosthesis 14 enlarges to
25 contact the internal walls of the vessel or hollow body
organ, as Fig. 3 shows. The catheter 10 can then be
withdrawn (as Fig. 10 shows).

It should be appreciated that the withdrawal
of the outer sheath 18 and the withdrawal of the
30 releasing means 28 can be accomplished in a single step
process. In this arrangement, a single activation
mechanism can be jointly coupled to the outer sheath 18
and the releasing means 28, so that the outer sheath 18
and releasing means 28 are withdrawn in a single step.

III. ALTERNATIVE EMBODIMENTS

In the embodiment shown in Figs. 11A to 11C (as already described), the distal end of a movable component of the releasing means 28 (e.g., the wire 58) extends along the central shaft 22 in a manner prescribed and controlled by the restraining means 26, i.e., between a tube 56 carried by the central shaft 22 and a recess 40 located in the proximal end of the catheter tip component 24. It is in the region between the tube 56 and the recess 40, that a stationary component of the releasing means 28, which is attached to the prosthesis 14 (e.g., the suture loops 44), is operatively coupled to the movable component of the releasing means 28. Movement of the movable component 58 out of this region releases the stationary component 44. The overall objective of the restraining means 26 is achieved: the restraining means 26 serves to maintain the movable component 58 of the releasing means 28 in a desired operative alignment with the central shaft 22, as well as in a desired operative relationship with the stationary component 44 of the releasing means 28, such that quick and certain release of the prosthesis 14 occurs.

The releasing means 28 and the restraining means 26 can be variously constructed to meet this objective. For example, in the alternative embodiment shown in Fig. 12A, the distal end of the movable component 58 of the releasing means 28 extends along the central shaft 22 in a manner prescribed and controlled by the restraining means 26, i.e., between adjacent, spaced apart tubes 60A and 60B, without dependence upon additional support by the catheter tip component 24. Each tube 60A and 60B surrounds the central shaft 22 in the same fashion as the single tube 56 shown in Figs. 11A to 11C. The movable component 58 of the releasing means 28 is held in the region between the two

tubes 60A and 60B in operative association with the stationary component 44 of the releasing means 28, and can be quickly and certainly withdrawn from this region to release the prosthesis 14. In a similar alternative arrangement (see Fig. 12B), the distal end of the movable component 58 of the releasing means 28 extends along the central shaft 22 between adjacent, spaced apart external tubes 62A and 62B, again without dependence upon additional support by the catheter tip component 24. In Fig. 12B, the tubes 62A and 62B project along the exterior of the central shaft 22, but do not surround it. Still, it should be appreciated that a single external support tube like tube 62A or 62B could, alternatively, be used in a hybrid combination with the recess 40 in the catheter tip component 24, if desired.

In another illustrative, alternative embodiment (see Fig. 13A), the distal end of the movable component 58 of the releasing means 28 extends within a lumen in the 66 central shaft 22, exiting through an aperture 64 in the shaft 22 and into a recess 40 in the catheter tip component 24. The movable component 58 of the releasing means 28 is held in the region between the aperture 64 and the recess 40 in operative association with the stationary component 44 of the releasing means 28, and can be quickly and certainly withdrawn from this region to release the prosthesis 14. In a similar alternative arrangement (see Fig. 13B), the distal end of the movable component 58 of the releasing means 28 extends within a lumen 68 the central shaft 22 between adjacent, spaced apart apertures 70 and 72. The movable component 58 exits the aperture 72 and enters a recess 40 in the catheter tip component 24. The movable component 58 of the releasing means 28 is held in the region between the aperture 72 and the recess 40 in operative association with the stationary component 44 of the

releasing means 28, and can be quickly and certainly withdrawn from this region to release the prosthesis 14.

In yet another illustrative, alternative embodiment (see Figs. 14A and 14B), the restraining means
5 26 includes a single tube 74 carried by the central shaft 22, through which the movable component 58 of the releasing means 28 passes. The tube 74 can comprise a surrounding tube of the type shown in Fig. 12A (as Figs. 14A and 14B show) or an external tube of the type shown
10 in Fig. 12B.

In this arrangement, the releasing means 28 includes a suture loop 76 carried by the proximal end of the catheter tip component 24 and a cutting element 78 carried on the distal end of the movable component 58 of
15 the releasing means 28. The suture loop 76 passes through the suture loops 44 on the prosthesis 14, as well as through the cutting element 78. The cutting element 78 on the distal end of the movable component 58 of the releasing means 28 extends along the central shaft 22 in
20 a manner prescribed and controlled by the restraining means 26, i.e., through and beyond the tube 74, and in operative association with the suture loops 44 and 76, which, in this embodiment, comprise the stationary components of the releasing means 28. This occurs without
25 dependence upon additional support by the catheter tip component 24. Withdrawal of the movable component 58 moves the cutting element 78 through the suture loop 76, cutting the suture loop 76 and releasing the prosthesis 14 (as Fig. 14B shows).

30 In yet another illustrative, alternative embodiment (see Figs. 15A and 15B), the restraining means 26 includes a single tube 80 carried by the central shaft 22, through which the movable component 58 of the releasing means 28 passes. As the tube 74 shown in Figs.
35 14A and 14B, the tube 80 can comprise a surrounding tube

of the type shown in Fig. 12A (as Figs. 15A and 15B show) or an external tube of the type shown in Fig. 12B.

In this arrangement, the releasing means 28 includes a wedge element 84 carried on the distal end of the movable component 58 of the releasing means 28. The wedge element 84 nests within a mating wedge surface 86 formed in the proximal end of the catheter tip component 24. Advancement of the movable component 58 moves the wedge element 84 into the registration within the wedge surface 86 (as Fig. 15A shows) and out of registration with the wedge surface 86 (as Fig. 15B shows). The releasing means 28 in this arrangement further includes alternative embodiments of suture loops 82 or 82', which are pinched between the wedge element 84 and the wedge surface 86 when the element 84 and the surface 86 are in registration, as Fig. 15A shows. The embodiment of the suture loop 82 comprises a closed loop 82 carried by a prosthesis stent 48. The embodiment of the suture loop 82' comprises an open loop 82' carried by the proximal end of the catheter tip component 24 and looped through a prosthesis stent 48. When either embodiment of the suture loop 82 or 82' is pinched between the wedge element 84 and the indented surface 86, expansion of the prosthesis 14 is restrained (as Fig. 15A shows). When the movable component 58 of the releasing means 28 is advanced proximally, the wedge element 84 is freed from registration within the wedge surface 86, freeing the loops 82 or 82', thereby releasing the prosthesis 14 for expansion, as Fig. 15B shows.

The preferred embodiments of the invention are described above in detail for the purpose of setting forth a complete disclosure and for the sake of explanation and clarity. Those skilled in the art will envision other modifications within the scope and spirit of the present disclosure.

The above described embodiments of this invention are merely descriptive of its principles and are not to be limited. The scope of this invention instead shall be determined from the scope of the
5 following claims, including their equivalents.

We Claim:

1. An apparatus for delivering a prosthesis comprising
a catheter sized and configured for
5 introduction into a hollow body organ or blood vessel,
the catheter having a distal end,
a carrier on the distal end sized and
configured to carry the prosthesis during introduction of
the catheter,
10 a release mechanism on the distal end being
operable to retain the prosthesis on the carrier, the
release mechanism also being operable to selectively
release the prosthesis from the carrier for deployment in
the hollow body organ or blood vessel,
15 an enclosure mechanism on the distal end being
operable to enclose the prosthesis on the carrier, the
enclosure mechanism also being operable to selectively
expose the prosthesis on the carrier, to thereby enable
the release of the prosthesis from the carrier in
20 response to selective operation of the release mechanism,
and
at least one actuator coupled to the release
mechanism and the enclosure mechanism to selectively
operate the release mechanism and the enclosure
25 mechanism.
2. An apparatus according to claim 1
wherein the at least one actuator includes a first
actuator coupled to the release mechanism and a second
actuator coupled to the enclosure mechanism.
- 30 3. An apparatus according to claim 2
wherein the catheter includes a proximal end and a handle
on the proximal end, and
wherein the at least one actuator is carried
by the handle.
- 35 4. An apparatus according to claim 1

wherein the release mechanism includes a fastening member releasably securing the prosthesis to the carrier.

5 5. An apparatus according to claim 4
 wherein the fastening member comprises a wire.

 6. An apparatus according to claim 1
 wherein the enclosure mechanism includes a sheath movable in a distal direction along the distal end to cover and enclose the prosthesis and in a proximal
10 direction along the distal end to uncover and expose the prosthesis.

 7. An apparatus according to claim 1
 wherein the catheter includes a lumen that accommodates passage of a guide wire.

15 8. A method for deploying an endovascular prosthesis comprising the steps of

 (i) providing an apparatus as defined in claim 1 or 2 or 3 or 4 or 5 or 6 or 7,

 (ii) operating the release mechanism to retain
20 the prosthesis on the carrier,

 (iii) operating the enclosure mechanism to enclose the prosthesis on the carrier

 (iv) after steps (ii) and (iii) introducing the catheter into a hollow body organ or blood vessel,
25 and

 (v) after step (iv), operating the enclosure mechanism and the release mechanism to expose and release the prosthesis from the carrier.

 9. A method according to claim 8
30 wherein step (v) comprises operating the enclosure mechanism and the release mechanism separately.

 10. A method according to claim 8
 further including the step of fastening the prosthesis to body tissue.

35 11. A system comprising

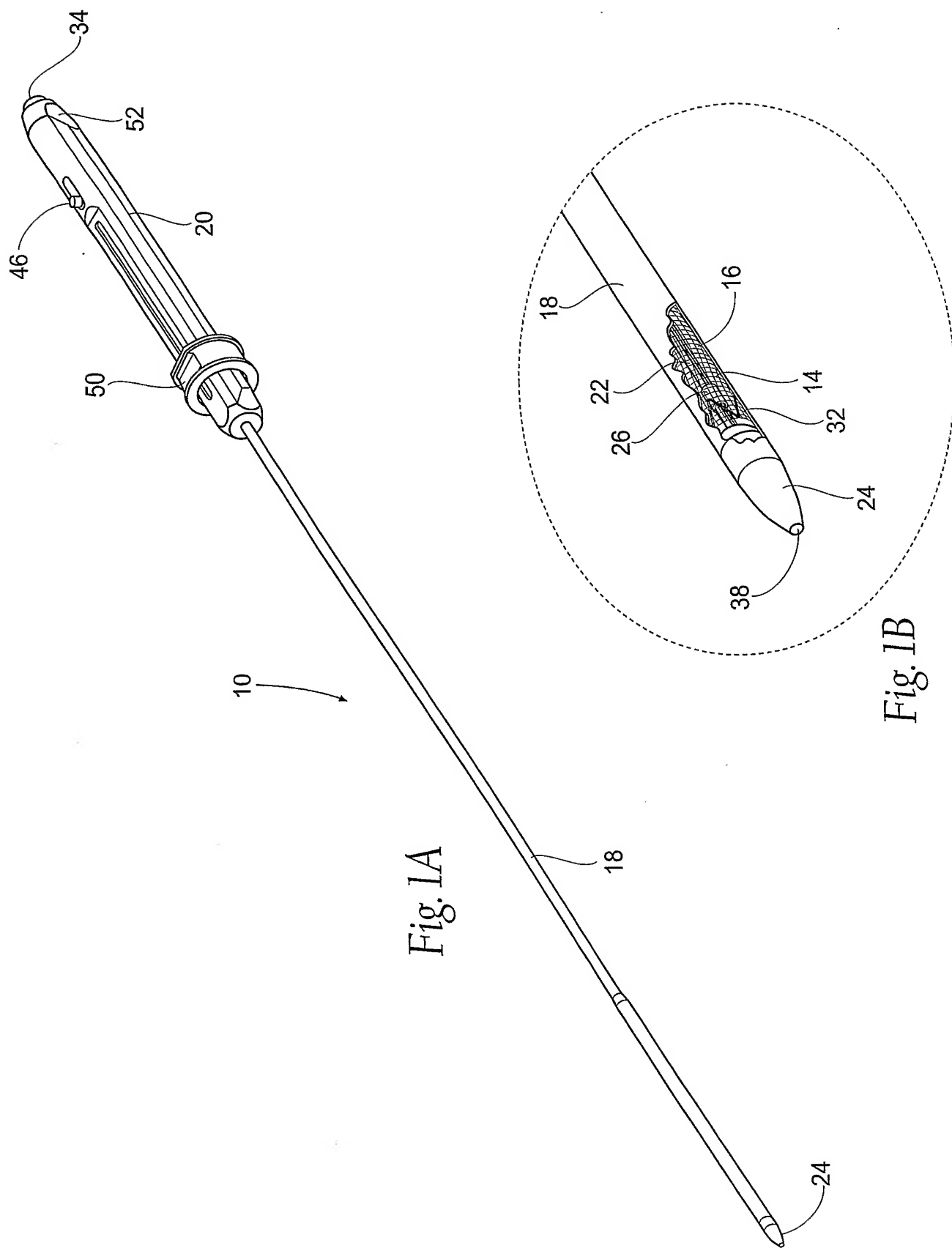
a prosthesis sized and configured for deployment in a hollow body organ or a blood vessel, and an apparatus as defined in claim 1 or 2 or 3 or 4 or 5 or 6 or 7 for delivering the prosthesis.

5 12. A system according to claim 11 wherein the prosthesis comprises a stent structure.

 13. A system according to claim 11 wherein the prosthesis comprises a malleable
10 stent structure.

 14. A system according to claim 11 wherein the prosthesis comprises a self-expanding stent structure.

 15. A system according to claim 11
15 wherein a region of the prosthesis is sized and configured to receive a fastening element to secure the prosthesis to body tissue.



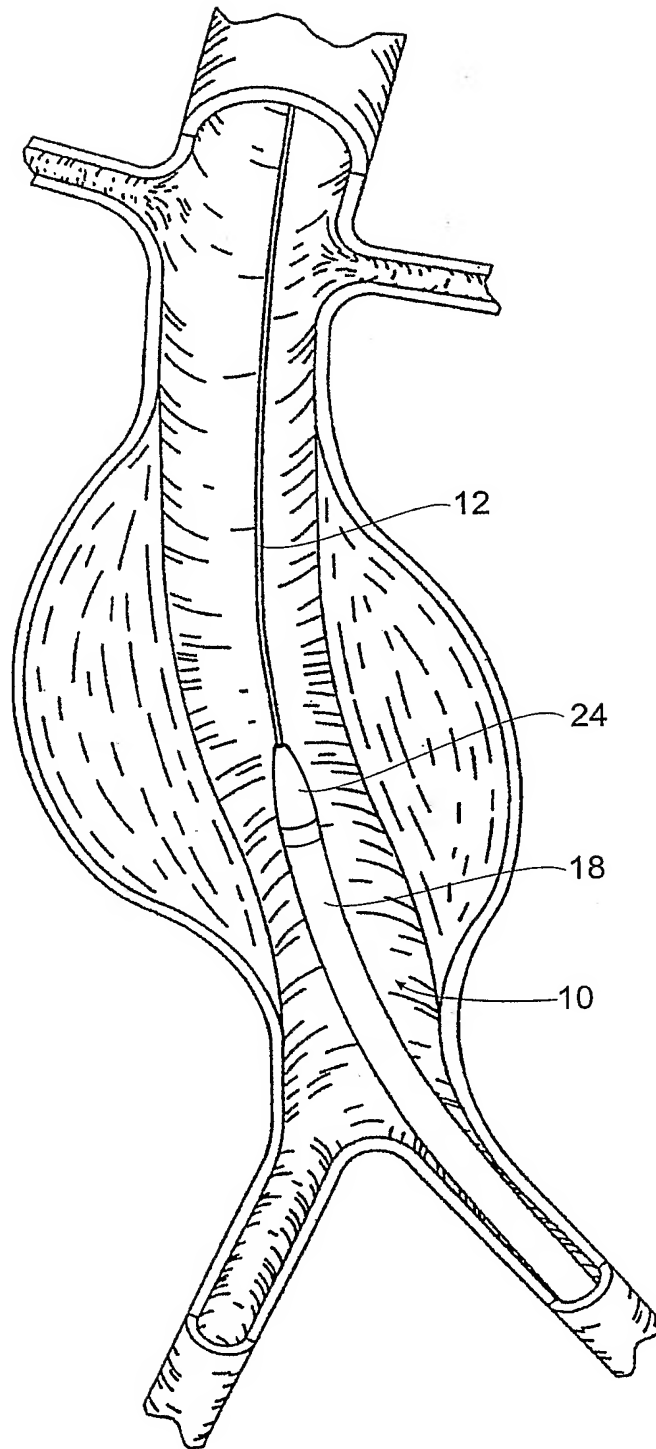


Fig. 2

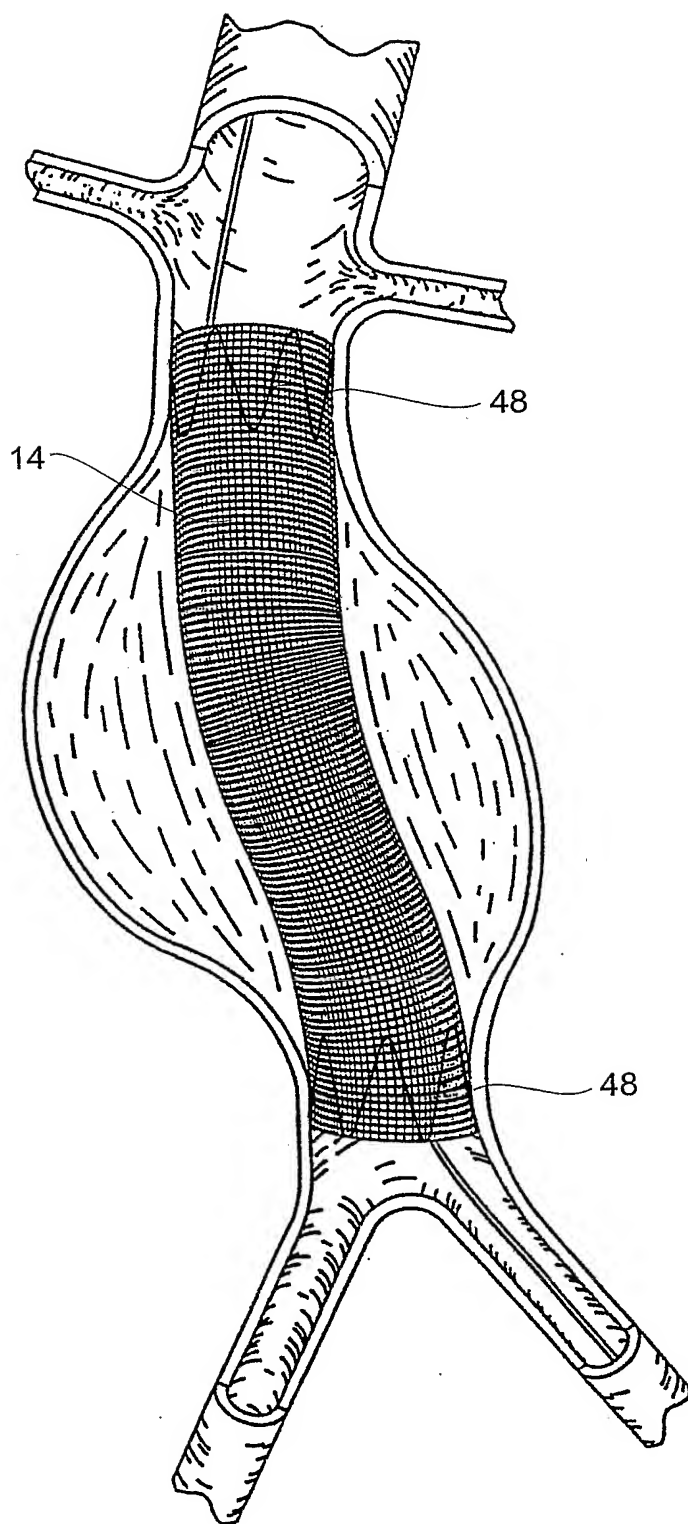


Fig. 3

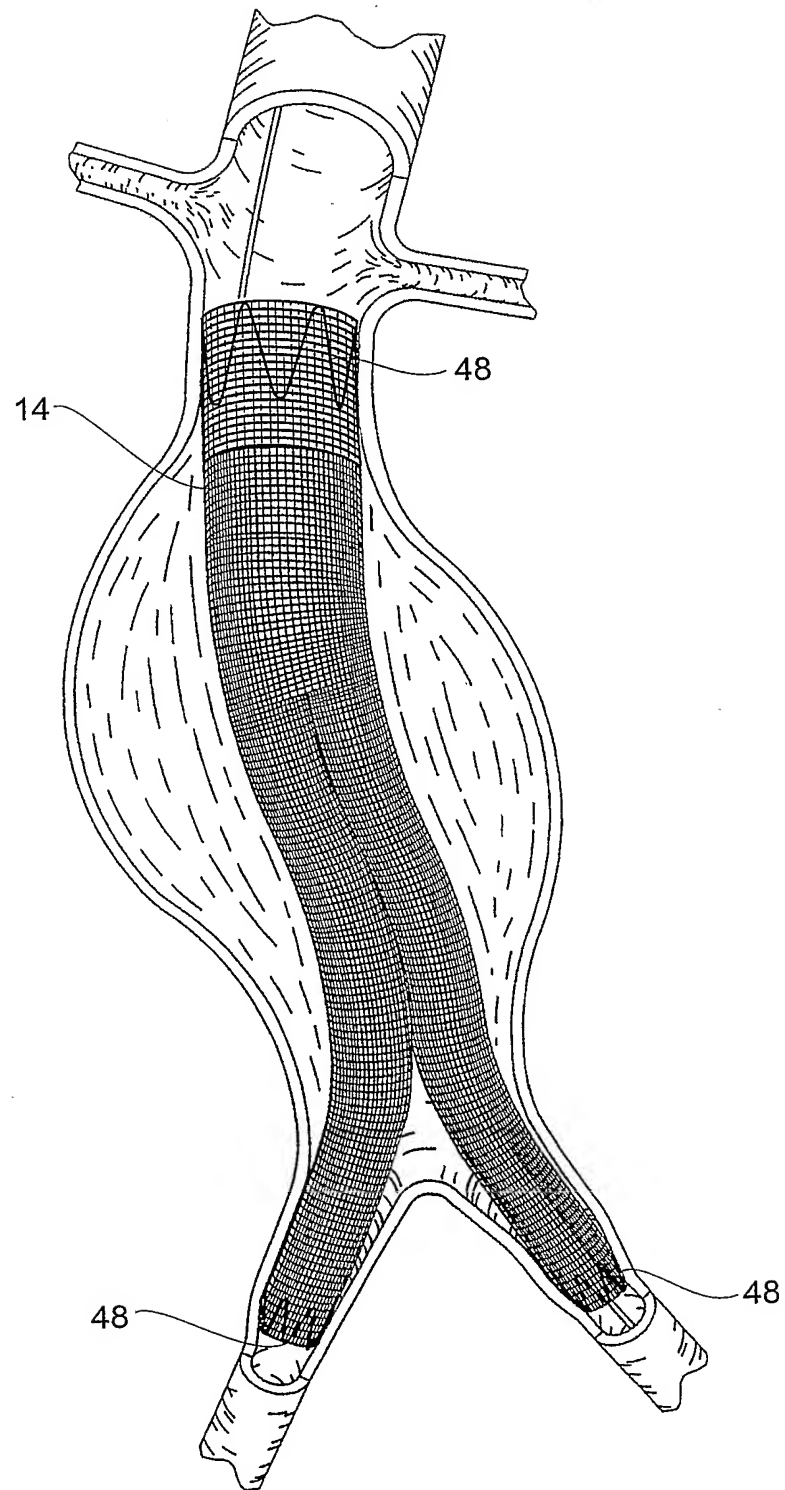


Fig. 4

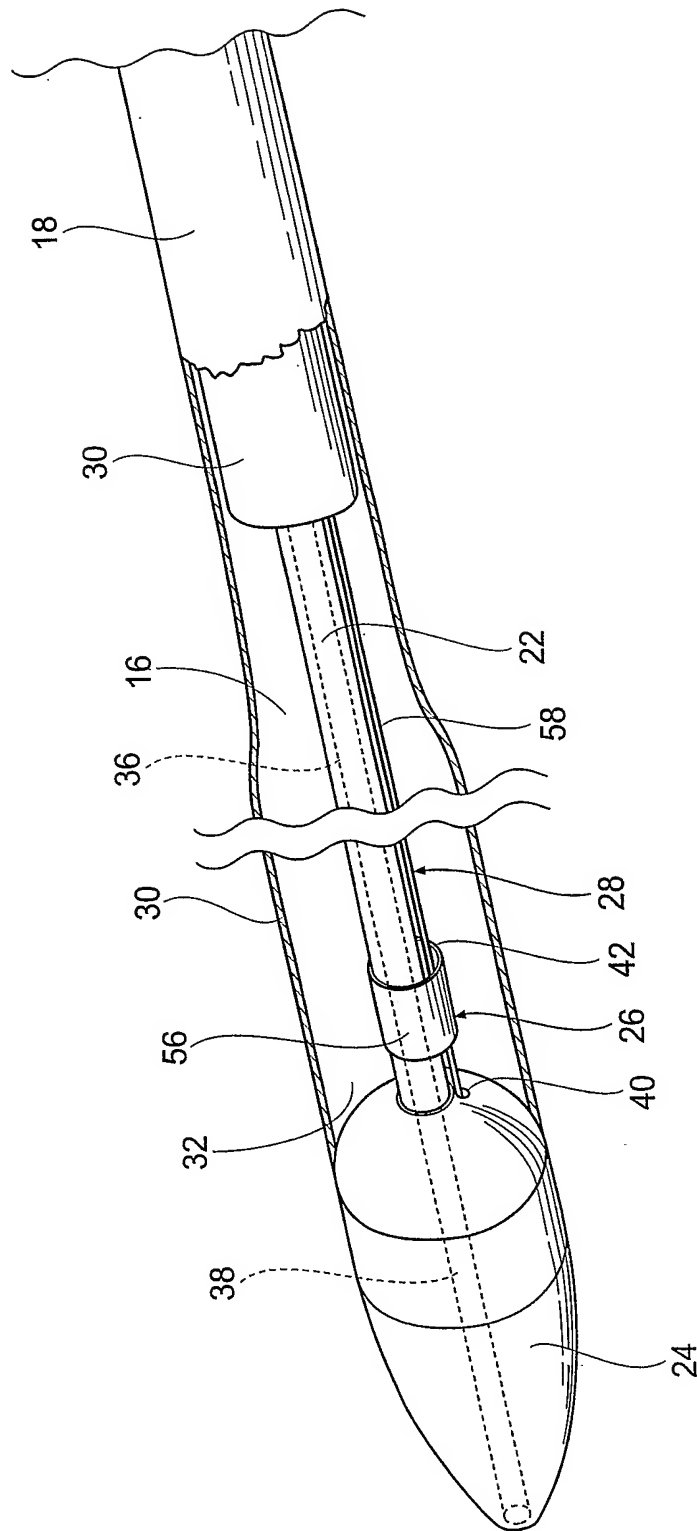


Fig. 5A

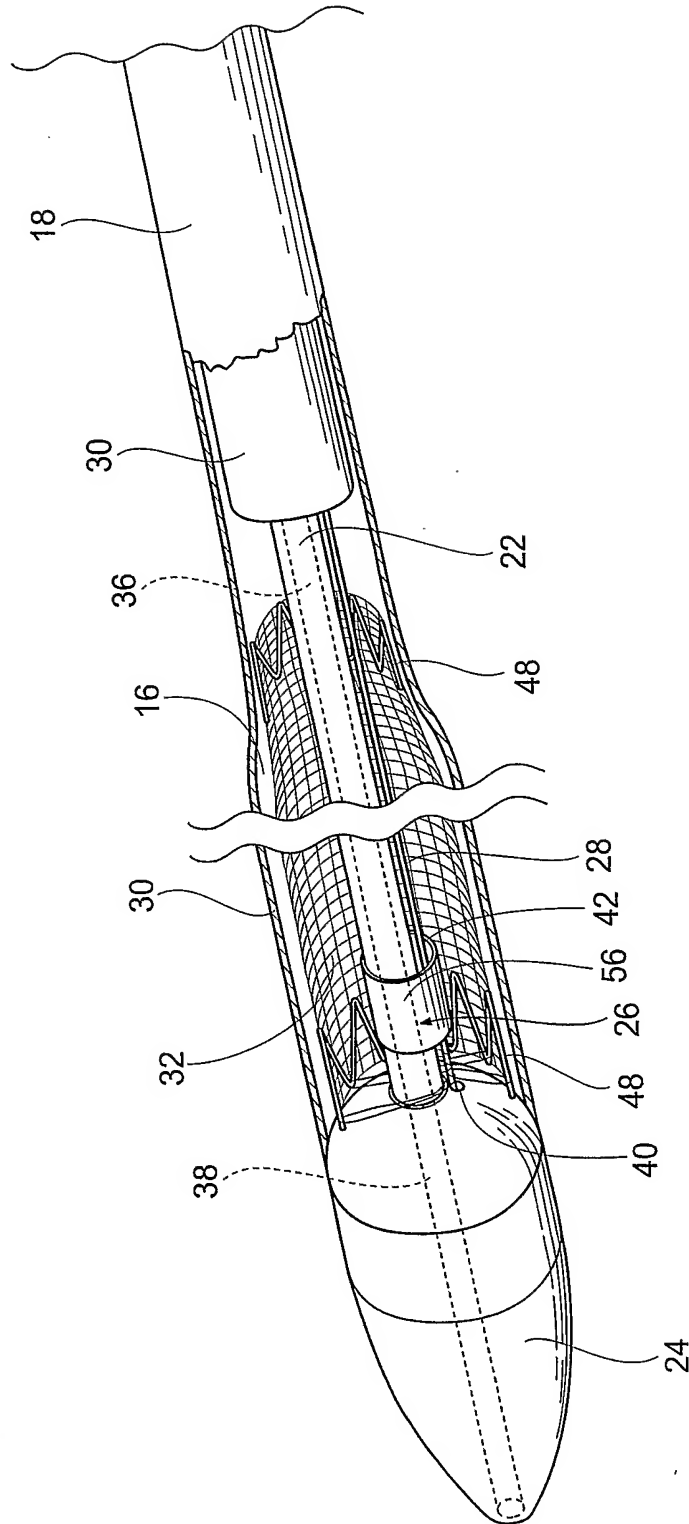


Fig. 5B

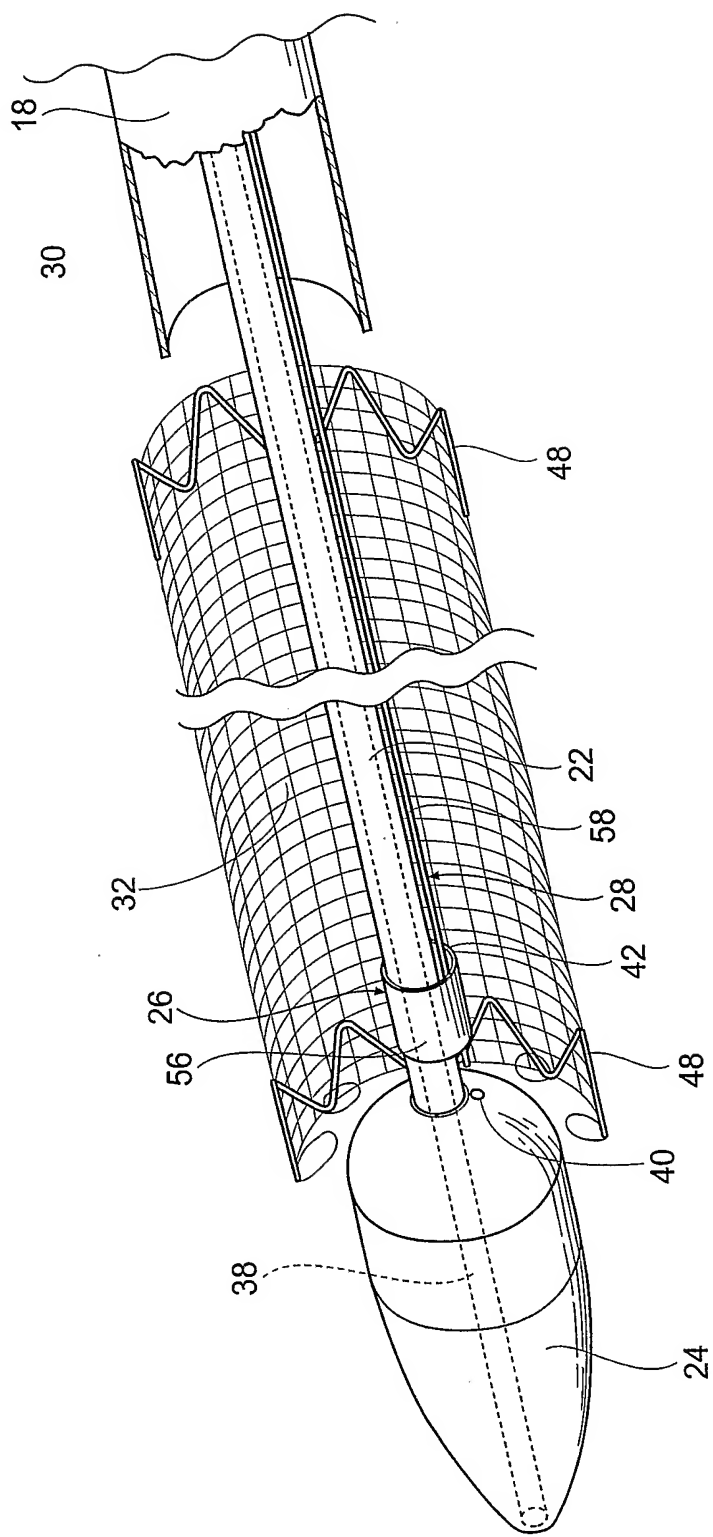


Fig. 5C

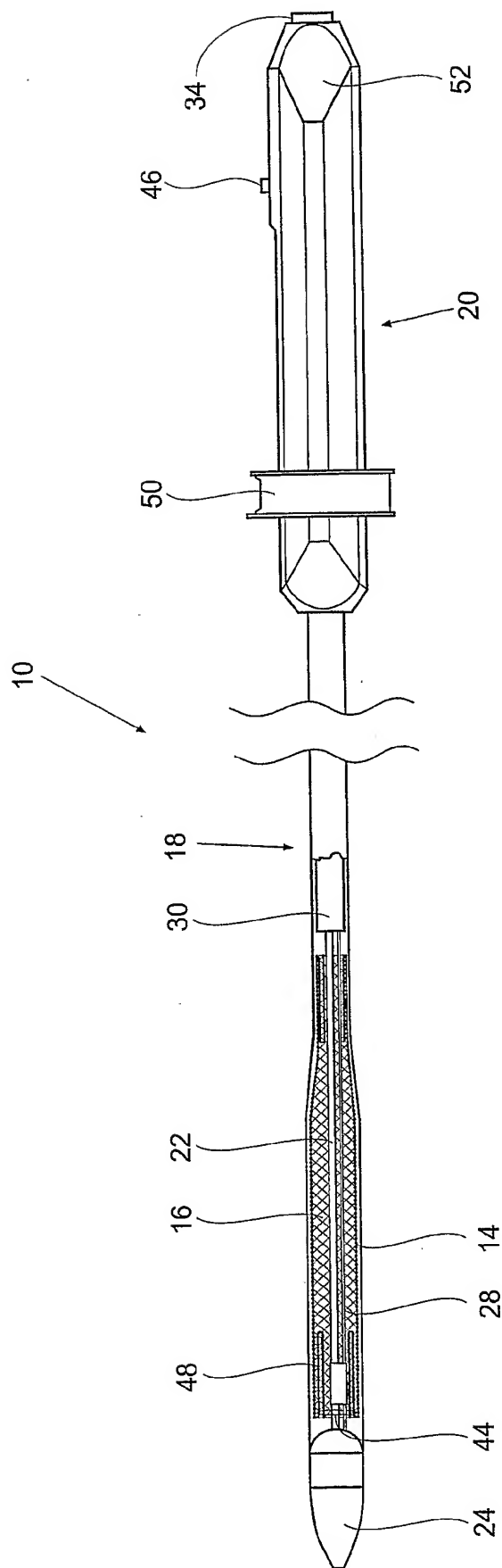


Fig. 6

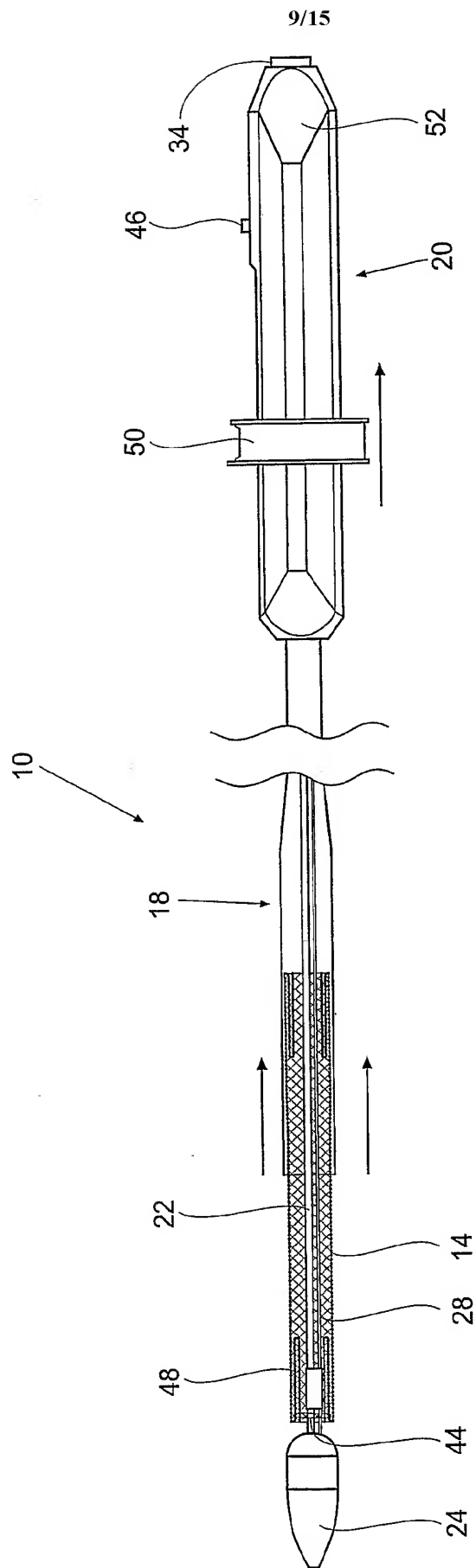


Fig. 7

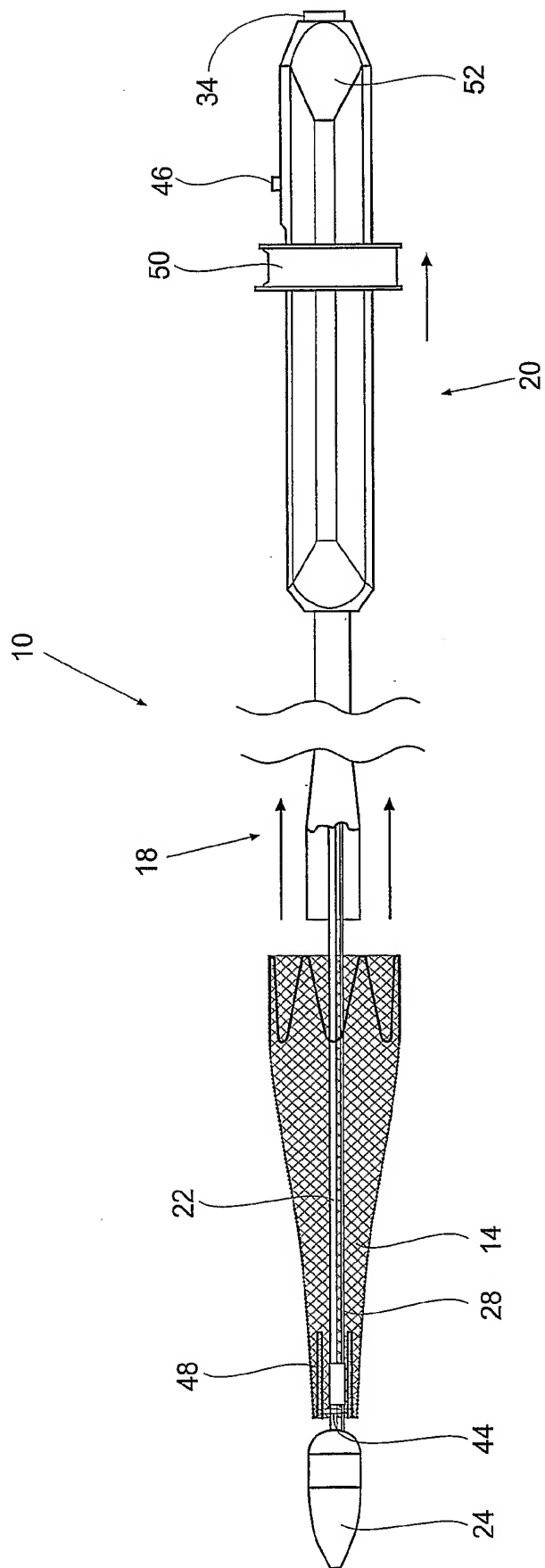


Fig. 8

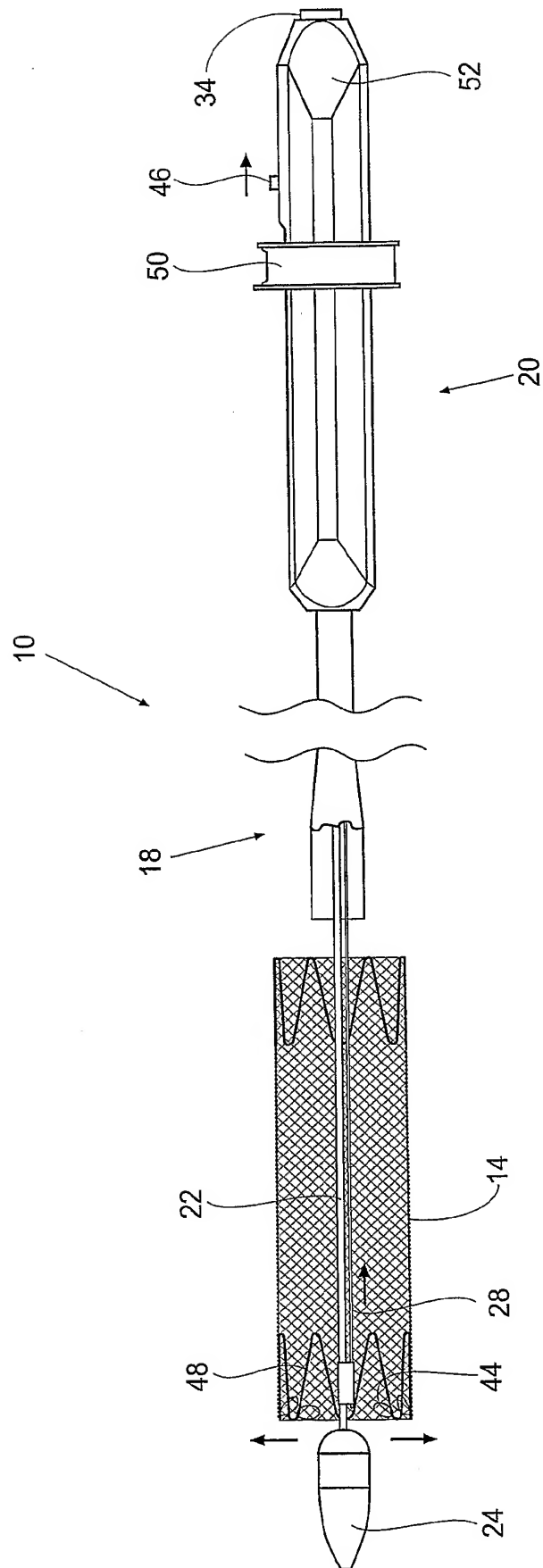


Fig. 9

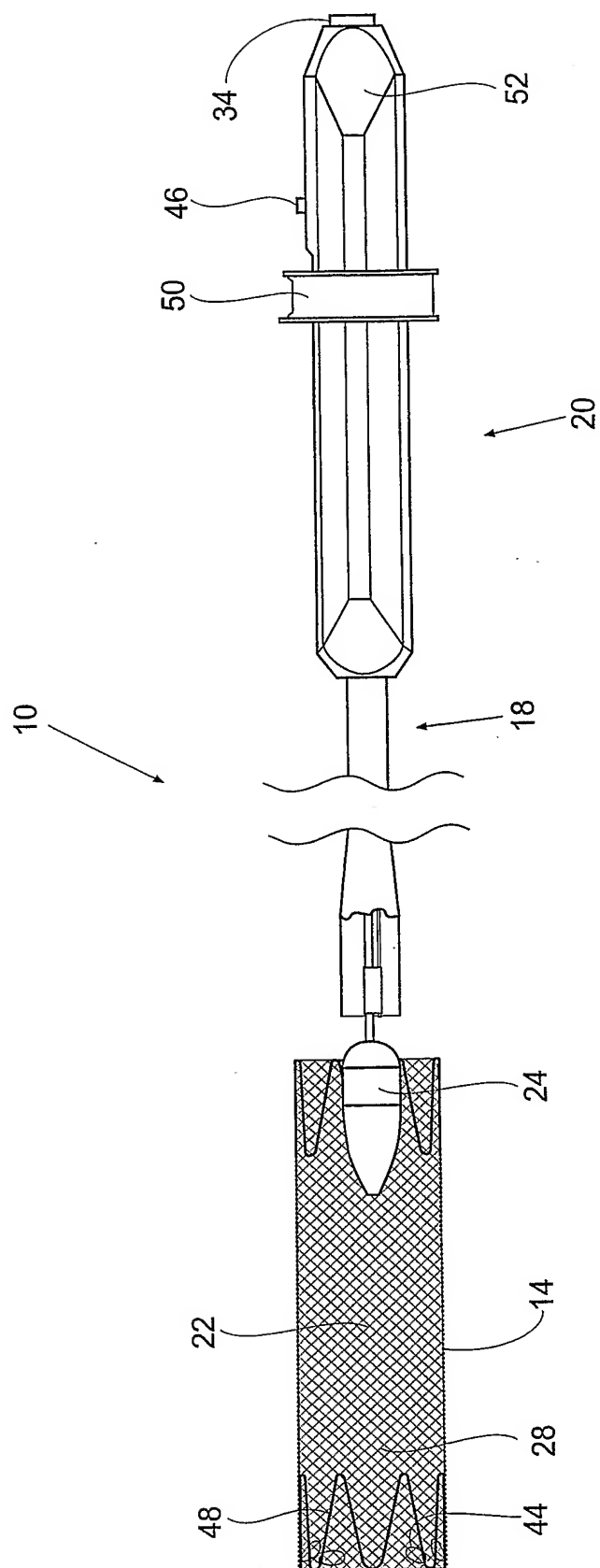


Fig. 10

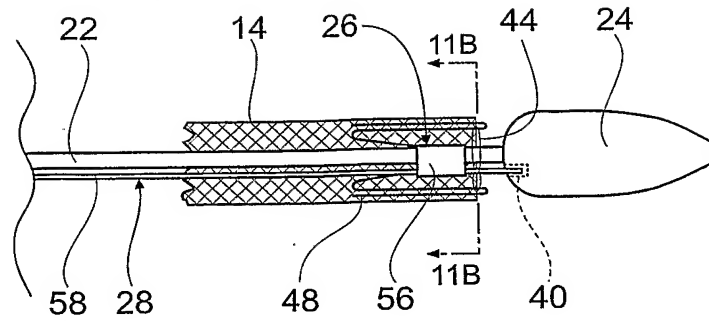


Fig. 11A

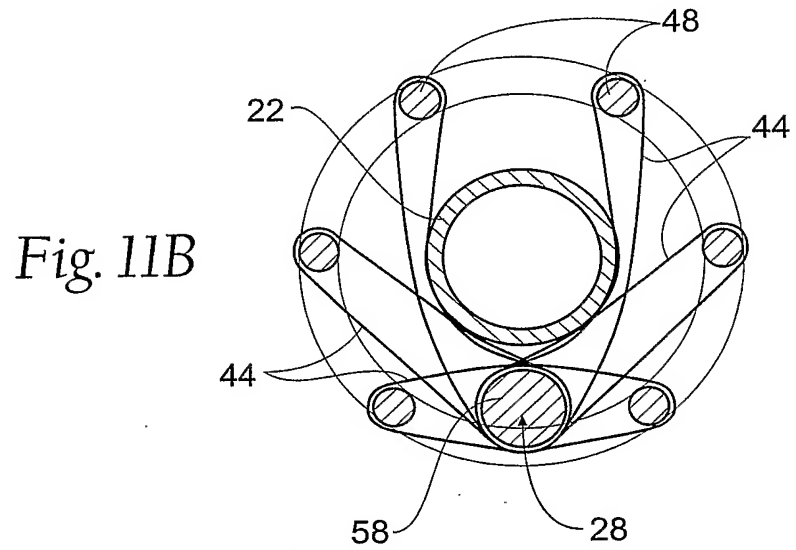


Fig. 11B

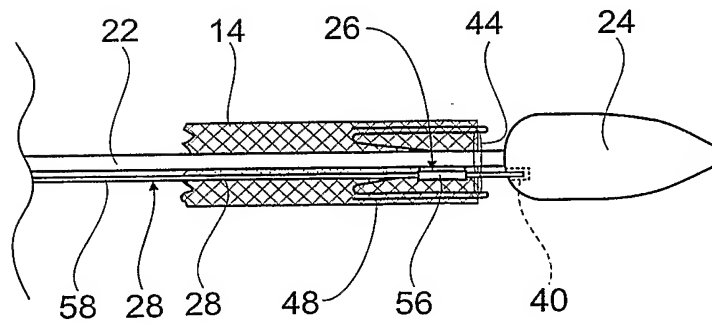


Fig. 11C

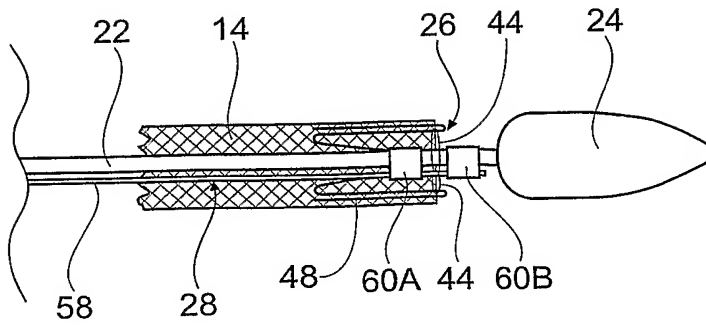


Fig. 12A

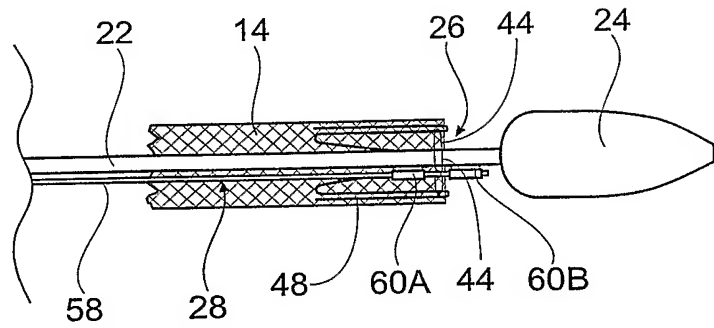


Fig. 12B

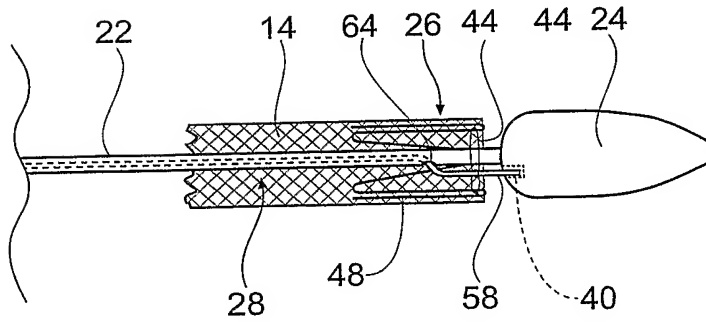


Fig. 13A

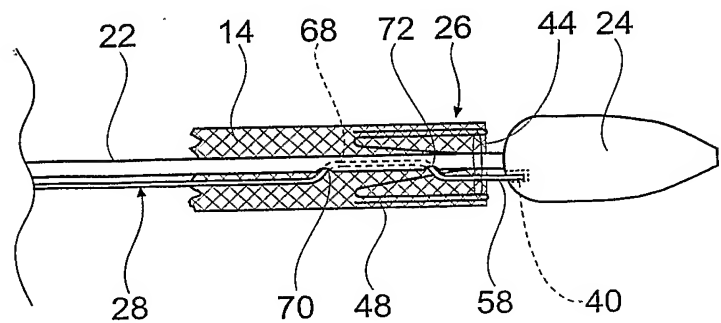


Fig. 13B

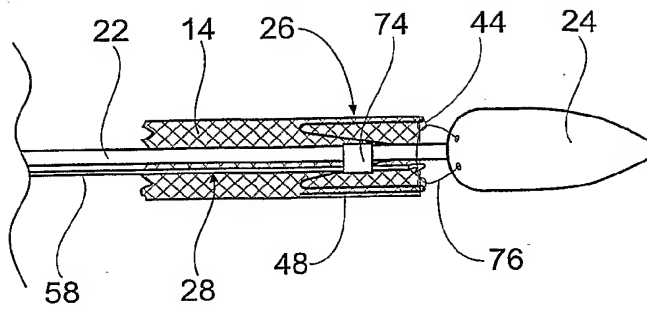


Fig. 14A

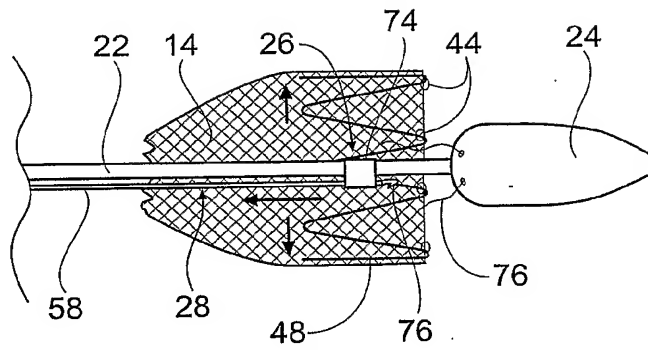


Fig. 14B

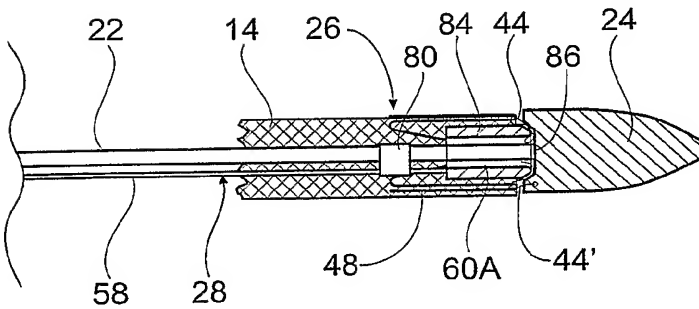


Fig. 15A

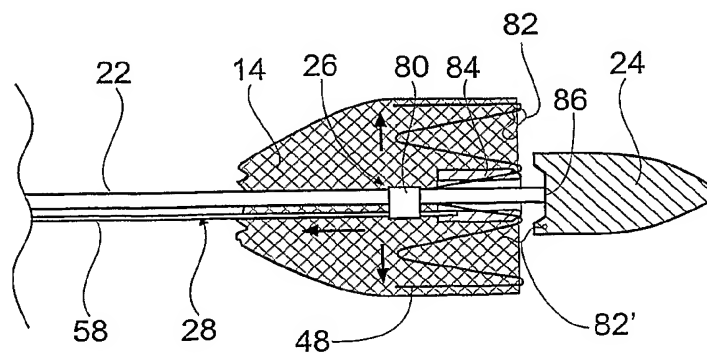


Fig. 15B

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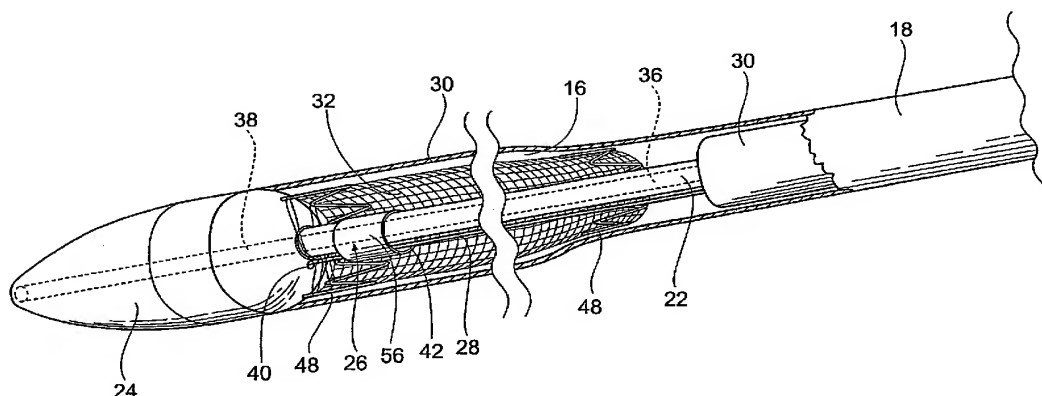
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(54) Title: PROSTHESIS DELIVERY SYSTEMS AND METHODS



(57) **Abstract:** Apparatus and method deliver a prosthesis into a hollow body organ or blood vessel. The systems and methods make use of a catheter. A carrier on the distal end of the catheter is sized and configured to carry the prosthesis. A release mechanism and an enclosure mechanism on the distal end are operable to retain and enclose the prosthesis on the carrier. The release mechanism and the enclosure mechanism are also operable to selectively expose and release the prosthesis from the carrier for deployment in the hollow body organ or blood vessel.

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Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,534,007 A (ST. GERMAIN et al) 09 July 1996 (09.07.1996), figures 1-3.	1-15
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
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(54) Title: SYSTEMS AND METHODS FOR ATTACHING A PROSTHESIS WITHIN A BODY LUMEN OR HOLLOW OR-
GAN

(57) Abstract: Systems and methods introduce and deploy prosthesis into a blood vessel or hollow body organ by intra-vascular access. The prosthesis is secured in place by fasteners which are implanted by an applier that is also deployed by intra-vascular access. The applier is configured to permit controlled, selective release of the fastener in a step that is independent of the step of implantation.



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**SYSTEMS AND METHODS FOR ATTACHING A PROSTHESIS
WITHIN A BODY LUMEN OR HOLLOW ORGAN**

Related Applications

This application claims the benefit of United
5 States Patent Application Serial No. 10/693,255, filed
October 24, 2003, and entitled "Multi-Lumen Prosthesis
Systems and Methods." This application also claims the
benefit of United States Patent Application Serial No.
10/307,226, filed November 29, 2002, and entitled
10 "Intraluminal Prosthesis Attachment Systems and Methods."

Field of the Invention

The invention relates generally to prostheses,
and in particular, the attachment of prostheses used in
the repair of diseased and/or damaged sections of a
15 hollow body organ and/or a blood vessel.

Background of the Invention

The weakening of a vessel wall from damage or
disease can lead to vessel dilatation and the formation
of an aneurysm. Left untreated, an aneurysm can grow in
20 size and may eventually rupture.

For example, aneurysms of the aorta primarily
occur in abdominal region, usually in the infrarenal area
between the renal arteries and the aortic bifurcation.
Aneurysms can also occur in the thoracic region between
25 the aortic arch and renal arteries. The rupture of an

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aortic aneurysm results in massive hemorrhaging and has a high rate of mortality.

Open surgical replacement of a diseased or damaged section of vessel can eliminate the risk of vessel rupture. In this procedure, the diseased or damaged section of vessel is removed and a prosthetic graft, made either in a straight or bifurcated configuration, is installed and then permanently attached and sealed to the ends of the native vessel by suture. The prosthetic grafts for these procedures are usually unsupported woven tubes and are typically made from polyester, ePTFE or other suitable materials. The grafts are longitudinally unsupported so they can accommodate changes in the morphology of the aneurysm and native vessel. However, these procedures require a large surgical incision and have a high rate of morbidity and mortality. In addition, many patients are unsuitable for this type of major surgery due to other co-morbidities.

Endovascular aneurysm repair has been introduced to overcome the problems associated with open surgical repair. The aneurysm is bridged with a vascular prosthesis, which is placed intraluminally. Typically these prosthetic grafts for aortic aneurysms are delivered collapsed on a catheter through the femoral artery. These grafts are usually designed with a fabric material attached to a metallic scaffolding (stent) structure, which expands or is expanded to contact the internal diameter of the vessel. Unlike open surgical aneurysm repair, intraluminally deployed grafts are not sutured to the native vessel, but rely on either barbs extending from the stent, which penetrate into the native vessel during deployment, or the radial expansion force of the stent itself is utilized to hold the graft in position. These graft attachment means do not provide the same level of attachment when compared to suture and can

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damage the native vessel upon deployment.

Summary of the Invention

The invention provides apparatus, tools, systems, and methods for repairing diseased and/or damaged sections of a hollow body organ and/or a blood vessel. The apparatus, tools, systems, and methods find use, e.g., in the introduction and deployment of a prosthesis into a blood vessel or hollow body organ, which desirably is achieved by intra-vascular access. The prosthesis is secured in place by fasteners, which are implanted by the apparatus, tools, systems, and methods that embody one or more features of the invention, which are also desirably deployed by intra-vascular access.

According to one aspect of the invention, the applier is configured to permit controlled, selective release of the fastener in a step that is independent of the step of implantation. According to one embodiment of this aspect of the invention, the applier includes a driven member that is carried on a tool body. The tool body can include, e.g., a tube, such as a catheter, to permit intra-vascular deployment of the driven member. The driven member is operable to apply an implantation force to the fastener. A drive actuator operates the driven member. The applier also includes a fastener-engaging mechanism on the driven member. The mechanism is operable in a first condition to couple the fastener to the driven member to transfer the implantation force from the driven member to the fastener. Implantation of the fastener can thereby be achieved. The mechanism is also operable in a second condition to release the fastener from the driven member. According to this aspect of the invention, the mechanism includes a second actuator, which places the mechanism in the second condition, to release the fastener. The second actuator is operable independent of the drive actuator. There can thus be a

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definite, stepwise separation between implanting the fastener in tissue using the implantation tool and releasing the fastener from the implantation tool after implantation is satisfactorily achieved.

5 Another aspect of the invention provides a tool that can be used to apply an implantation force to a fastener, which is sized and configured for implantation in tissue in response to an implantation force applied according to prescribed conditions. The tool is coupled
10 to a controller, which interrupts implantation before it is completed, and interjects a "go"/"no go" decision-making step before proceeding further. The tool includes a driven member carried on a tool body. The tool body can comprise, e.g., a tube, such as a catheter. The driven
15 member is operable to apply the implantation force. A mechanism on the driven member couples the fastener to the driven member to transfer the implantation force from the driven member to the fastener. According to this aspect of the invention, a controller is coupled to the
20 driven member. The controller executes differing operational phases during the implantation process. During an initial phase the driven member is operated to apply the implantation force under conditions that do not achieve the prescribed conditions, so that only partial
25 implantation of the fastener occurs. A lull phase commences at the end of the initial phase. The lull phase interrupts operation of the driven member. There is a final phase, which operates the driven member under conditions that supplement the conditions of the initial
30 phase to achieve the prescribed conditions, and thus achieve complete implantation. However, the controller requires, after the initial phase, a prescribed command to advance from the lull phase to the final phase. The lull phase requires a decision be made before
35 implantation of the fastener is finalized. If

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implantation during the initial phase is deemed not to be satisfactory, implantation can be aborted, and the fastener (now only partially implanted) can be withdrawn. The decision can comprise a conscious decision by the operator and/or a decision based, at least in part, upon physuical or operational conditions sensed during the initial phase.

Another aspect of the invention provides a tool for applying an implantation force to a fastener that is sized and configured for implantation in tissue in response to an implantation force. The tool comprises a driven member carried on a tool body that is operable to apply the implantation force. According to this aspect of the invention, an element is included that tethers the fastener to the tool body. The tethering element safeguards against inadvertent loss of the fastener prior to implantation. The tethering element includes a frangible portion, so that, once the fastener is satisfactorily implanted, the tethering element can be parted from the fastener and the tool body removed.

The invention also provides various systems and methods for using the above-described devices to implant tissue in a vessel or hollow body organ.

Other features and advantages of the invention shall be apparent based upon the accompanying description, drawings, and claims.

Brief Description of the Drawings

The invention will be understood from the following detailed description of preferred embodiments, taken in conjunction with the accompanying drawings, wherein:

Fig. 1 is a perspective view of a prosthesis having a fastening region that accommodates the introduction of one or more fasteners.

Fig. 2 is a perspective view of the prosthesis

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shown in Fig. 1, showing the attachment of fasteners in the fastening region.

Fig. 3 is a perspective view of the prosthesis shown in Fig. 1 positioned within an abdominal aortic aneurysm.

Fig. 4 is a perspective view of the prosthesis shown in Fig. 3 as it is being deployed by an intra-vascular catheter.

Fig. 5 is a perspective view of the prosthesis shown in Fig. 3 after it been deployed and as fasteners are being implanted by an intra-vascular fastener applier.

Fig 6. is a side view, partly broken away and in section, of an intra-vascular fastener applier that can be used to implant fasteners in the prosthesis shown in Figs. 1 and 2, in the manner shown in Fig. 5.

Fig. 7 is a perspective view of a type of helical fastener that can be implanted using the intra-vascular fastener applier shown in Fig. 6.

Fig. 8A(1) is an enlarged view of a carrier for implanting a fastener of the type shown in Fig. 7, the carrier being located at the distal end of an intra-vascular fastener applier of the type shown in Fig. 8A(2), the carrier being shown in a condition to receive a fastener prior to implantation.

Fig. 8A(2) is a side view, partly broken away and in section, of a fastener applier that includes, at its distal end, a carrier as shown in Fig. 8A(1), the carrier being shown after receipt of a fastener and as the carrier is being rotated to implant the fastener in a prosthesis/tissue wall.

Fig. 8B(1) is an enlarged view of the carrier shown in Fig. 8A(1), the carrier being shown in a condition to release a fastener after implantation.

Fig. 8B(2) is a side view, partly broken away

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and in section, of the fastener applier that includes, at its distal end, the carrier shown in Fig. 8B(1), the carrier being shown releasing a fastener following its implantation in a prosthesis/tissue wall.

5 Fig. 8C is a side view, partly broken away and in section, of the fastener applier shown in Fig. 8A(2), the carrier being shown withdrawing or retrieving a fastener from a prosthesis/tissue wall.

10 Fig. 9A(1) is an enlarged view of another embodiment of a carrier for implanting a fastener of the type shown in Fig. 7, the carrier being located at the distal end of an intra-vascular fastener applier of the type shown in Fig. 9A(2), the carrier being shown in a condition to receive a fastener prior to implantation.

15 Fig. 9A(2) is a side view, partly broken away and in section, of a fastener applier that includes, at its distal end, a carrier as shown in Fig. 9A(1), the carrier being shown after receipt of a fastener and as the carrier is being rotated to implant the fastener in a
20 prosthesis/tissue wall.

 Fig. 9B(1) is an enlarged view of the carrier shown in Fig. 9A(1), the carrier being shown in a condition to release a fastener after implantation.

25 Fig. 9B(2) is a side view, partly broken away and in section, of the fastener applier that includes, at its distal end, the carrier shown in Fig. 9B(1), the carrier being shown releasing a fastener following its implantation in a prosthesis/tissue wall.

30 Fig. 10A(1) is an enlarged view of a carrier for implanting a fastener of the type shown in Fig. 7, the carrier being located at the distal end of an intra-vascular fastener applier of the type shown in Fig. 10A(2), the carrier being shown in a condition to receive a fastener prior to implantation.

35 Fig. 10A(2) is a side view, partly broken away

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and in section, of a fastener applier that includes, at its distal end, a carrier as shown in Fig. 10A(1), the carrier being shown after receipt of a fastener and as the carrier is being rotated to implant the fastener in a prosthesis/tissue wall.

Fig. 10B(1) is an enlarged view of the carrier shown in Fig. 10A(1), the carrier being shown in a condition to release a fastener after implantation.

Fig. 10B(2) is a side view, partly broken away and in section, of the fastener applier that includes, at its distal end, the carrier shown in Fig. 10B(1), the carrier being shown releasing a fastener following its implantation in a prosthesis/tissue wall.

Fig. 11 is an enlarged view of a carrier for implanting a fastener of the type shown in Fig. 7, the carrier being located at the distal end of an intra-vascular fastener applier of the type shown in Figs. 10A(2) and 10B(2), the carrier being shown in a condition to receive a fastener prior to implantation.

Figs. 12A and 12B are perspective views of a fastener assembly comprising a helical fastener and a cap, Fig. 12A showing an exploded view of the assembly and Fig. 12B showing an assembled view of the assembly.

Figs. 13A and 13B are side views showing in interior of a carrier for implanting a fastener assembly of the type shown in Fig. 12B, the carrier being located at the distal end of an intra-vascular fastener applier of the type shown in Fig. 15A, the carrier in Fig. 13A being shown in a condition to receive the fastener assembly prior to implantation, the carrier in Fig. 13B being shown in a condition to release the fastener assembly after implantation.

Figs. 14A and 14B are side views showing the mounting of the fastener assembly shown in Fig. 12B to the carrier shown in Fig. 13A.

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Fig. 15A is a side view, partly broken away and in section, of a fastener applier that includes, at its distal end, a carrier as shown in Fig. 13A, the carrier being shown after receipt of a fastener assembly as shown in Fig. 14B and as the carrier is being rotated to implant the fastener assembly in a prosthesis/tissue wall.

Fig. 15B is a side view, partly broken away and in section, of a fastener applier shown in Fig. 15A, the carrier being shown releasing the fastener assembly after its implantation in a prosthesis/tissue wall.

Fig. 15C is a side view, partly broken away and in section, of a fastener applier shown in Fig. 15A, the carrier being shown withdrawing or retrieving the fastener assembly from a prosthesis/tissue wall.

Fig. 16A(1) is an enlarged view of a carrier for implanting a fastener of the type shown in Fig. 7, the carrier being located at the distal end of an intra-vascular fastener applier of the type shown in Fig. 16A(2), the carrier being shown holding a fastener prior to implantation.

Fig. 16A(2) is a side view, partly broken away and in section, of a fastener applier that includes, at its distal end, a carrier as shown in Fig. 16A(1), the carrier being rotated to implant the fastener in a prosthesis/tissue wall.

Fig. 16B is a side view, partly broken away and in section, of the fastener applier shown in Fig. 16A(2), the carrier being shown at the end of a first operating phase, during which the fastener has been partially implanted in a prosthesis/tissue wall and in which the fastener remains secured to the carrier.

Fig. 16C is a side view, partly broken away and in section, of the fastener applier shown in Fig. 16A(2), the carrier being shown following the first

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operating phase and at the end of a second operating phase, during which the fastener has been fully implanted and released from the carrier into a prosthesis/tissue wall.

5 Fig. 16D is a side view, partly broken away and in section, of the fastener applier shown in Fig. 16A(2), the carrier being shown following the first operating phase and during another operating phase, during which the fastener is being withdrawn or retrieved
10 from a prosthesis/tissue wall while still secured to the carrier.

 Figs. 17A and 17B are side views of a fastener applier of the type shown in any of the preceding Figures, the fastener applier including an element
15 releasably tethering a fastener to the fastener applier, Fig. 17A showing the tethering element holding on to the fastener following its implantation in a prosthesis/tissue wall, and Fig. 17B showing the tethering element after having been parted from the
20 fastener.

 Figs. 18A and 18B show an embodiment of a tethering element of the type shown in Figs. 17A and 17B, the tethering element being secure to a frangible portion of the fastener, Fig. 18A showing the tethering element
25 holding on to the fastener following its implantation in a prosthesis/tissue wall, and Fig. 18B showing the tethering element after having been parted from the fastener.

 Fig. 19A shows an embodiment of a tethering
30 element of the type shown in Figs. 17A and 17B, the tethering element being secured to a frangible joint that is broken by rotating the tethering element relative to the fastener.

 Fig. 19B shows an embodiment of a tethering
35 element of the type shown in Figs. 17A and 17B, the

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tethering element being secured to a frangible joint that is broken by pulling the tethering element from the fastener.

5 Figs. 20A and 20B show an embodiment of a tethering element of the type shown in Figs. 17A and 17B, the tethering element being secured to a screw joint (Fig. 20A) that is parted by rotating the tethering element relative to the fastener (Fig. 20B).

10 Figs. 21A and 21B show an embodiment of a tethering element of the type shown in Figs. 17A and 17B, the tethering element being secured to a ball joint (Fig. 21A) that is parted by pulling the tethering element away from the fastener (Fig. 21B).

15 Figs. 22A and 22B show an embodiment of a tethering element of the type shown in Figs. 17A and 17B, the tethering element being secured to a slip joint (Fig. 22A) that is parted by pulling the tethering element away from the fastener (Fig. 22B).

20 Figs. 23A and 23B show an embodiment of a tethering element of the type shown in Figs. 17A and 17B, the tethering element being secured to a knotted joint (Fig. 23A) that is parted by pulling the tethering element away from the fastener (Fig. 23B).

25 Figs. 24A and 24B show an embodiment of a tethering element of the type shown in Figs. 17A and 17B, the tethering element being secured to a frangible tube joint (Fig. 24A) that is parted by pulling a rip cord (Fig. 24B).

30 Figs. 25A and 25B show an embodiment of a tethering element of the type shown in Figs. 17A and 17B, the tethering element being secured by an interlocking joint (Fig. 25A) that is released by pulling away a slidable sleeve (Fig. 25B).

Detailed Description of the Invention

35 I. PROSTHESIS

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A. Structure

Fig. 1 shows a prosthesis 10. The prosthesis 10 serves to repair or reinforce a region of a vessel wall or hollow body organ which has been weakened by disease or damage.

In the illustrated embodiment (see Fig. 1), the prosthesis 10 comprises a tubular trunk 12. The trunk 12 is sized and configured to fit within a targeted region of a hollow body organ and/or a blood vessel. The targeted region is selected on the basis of certain anatomic characteristics. These characteristics include a weakened conditioned caused, e.g., by disease or damage.

The trunk 12 forms a generally cylindrical structure with an open interior lumen 18. In the illustrated embodiment, the trunk 12 includes a prosthetic material 14 supported by a scaffold 16. The prosthetic material 14 is selected on the basis of its biocompatibility, durability, and flexible mechanical properties. The material 14 can comprise, e.g., woven polyester or ePTFE.

The scaffold 16 is desirable sized and configured to permit non-invasive deployment of the prosthesis 10 by an intra-vascular catheter. With this criteria in mind, the scaffold 16 is sized and configured to assume a compressed or collapsed, low profile condition, to permit its intra-vascular introduction into the hollow body organ and/or blood vessel by a catheter, as will be described in greater detail later.

Also with this criteria in mind, the scaffold 16 is sized and configured for expansion *in situ* from its collapsed condition into an expanded condition in contact with tissue in the targeted region, as will also be described in greater detail later.

In this respect, the scaffold 16 can comprise, e.g., a malleable plastic or metal material that expands in the presence of an applied force. In this arrangement, the

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deployment catheter can include, e.g., an expandable body, such as a balloon, to apply the expansion force to the scaffold 16 *in situ*.

Alternatively, the scaffold 16 can comprise a self-expanding plastic or metal material that can be compressed in the presence of a force, but self-expands upon removal of the compressive force. In this arrangement, the deployment catheter can include, e.g., a sleeve that can be manipulated to enclosed the scaffold 16 in a collapsed condition, thereby applying the compressive force, and to release the scaffold 16 when desired to allow the scaffold 16 to self-expand *in situ*.

For self-expansion, the scaffold 16 can include individual self-expanding, zigzag type main stent rings 22. The main stent rings 22 can be made, e.g., from Nitinol® wire. Still, other materials, manufacturing methods and designs can be used.

The main stent rings 22 need not be attached to one another throughout the prosthesis material 14, as Fig. 1 shows. The individual main stent rings 22 allow for longitudinal compliance while maintaining radial support of the open interior lumen 18. This technical feature allows the prosthesis 10 to more readily accommodate changes in morphology in the targeted region. Still, it may be desirable in certain locations within the prosthesis structure to have attachments between the individual main stent rings 22 to provide enhanced stability and/or additional radial support.

Each of the main stent rings 22 can be, e.g., sewn onto prosthetic material 14. In the illustrated embodiment, in which the prosthetic material 14 is woven polyester, the attachment of the main stent rings 22 can be made, e.g., with polyester suture.

However, it is also contemplated that other attachment means could be utilized to secure the main

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stent rings 22 to the prosthetic material 14. These means include bonding; capturing the main stent rings 22 between two layers of prosthetic material 14; and incorporating the main stent rings 22 directly into the prosthetic material 14.

In certain locations it is desired to have the main stent rings 22 attached to the outer diameter of the prosthetic material 14. Still, it is also contemplated that the main stent rings 22 could be attached to the inner diameter of the prosthetic material 22.

At least one end of the trunk 12 desirably also includes one or more end stent rings 24. The principal purpose of an end stent ring 24 is to provide a seal between the trunk 12 and adjoining tissue. This sealing function is particularly desirable when the prosthesis 10 is deployed in a blood vessel or other body organ, where body fluids are intended to reside or pass through the prosthesis 10. The end sent rings 24 can also serve, with the main stent rings 22, to help maintain the position of the prosthesis 10 in the targeted region.

The trunk 12 (material 14 and/or scaffold 16) can carry radiopaque markers 46 to help fluoroscopically position the prosthesis 10. The markers 46 can take the form, e.g. of marker bands, tight wound coils, or wire made from radiopaque materials such as platinum, platinum/iridium, or gold.

The trunk 12 also desirably includes at least one fastening region 26 that accommodates the introduction of one or more fasteners 28 to anchor the prosthesis 10 in place (see Fig. 2). It is desirable that this region 26 of the trunk 12 be specially sized and configured for the receipt and retention of fasteners 28. For example, the size and spacing of ring stent patterns can be configured in the region 26 to specially accommodate the placement of fasteners; and/or woven fibers with an "X-pattern" or

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a "sinusoidal pattern" can be used in the region 26 to specially accommodate placement of fasteners; and/or the prosthetic material 14 can be folded-over to form multiple layers, to reinforce the prosthesis in the region 26 where fasteners are placed; and/or denser weave patterns or stronger fibers can be used, selected from, e.g., Kevlar™ material or Vectran™ material or metallic wire woven alone or interwoven with typical polyester fibers in the region 26 where fasteners are placed. It may also be desirable to fluoroscopically indicate this region 26 with auxiliary radiopaque markers 30 on the prosthetic material 14, and/or auxiliary stent rings 32 to aid in positioning the fasteners.

The fasteners 28 can be variously constructed. They can, e.g., comprise helical fasteners or staples.

Desirably, like the prosthesis 10 itself, the fasteners 28 are introduced by an intra-vascular fastener attachment assembly. Details of various fastener attachment assemblies will be described in greater detail later.

B. Use of the Prosthesis

The targeted region for deployment of the tissue reinforcement prosthesis 10 as just described can vary. In Fig. 3, the trunk 12 is sized and configured to extend, for purposes of illustration, in the aorta adjacent the renal arteries distally to a location proximal the natural bifurcation of the iliac arteries. However, this targeted site of deployment is selected for purposes of illustrating the features of the prosthesis 10, and it is not intended to be limiting.

As shown in Fig. 3, the fastening region 26 is located in the neck of the aorta adjacent to the renal arteries. The features of the fastening region 26, previously described, make possible the secure attachment of the prosthesis 10, without migration.

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In this arrangement (see Fig. 3), the trunk 12 may include a supra-renal stent 44 at its proximal end, which extends beyond the prosthetic material 14. When deployed within the aorta, this stent 44 would extend above the level of the renal arteries, as Fig. 3 shows. The supra-renal stent 44 orients the prosthesis 10 within the lumen and aids in maintaining the position of the prosthesis 10 in the aorta without obstructing the normal blood flow into the renal arteries.

During use (see Figs. 4 and 5), a first catheter 20 is navigated over a guide wire 48 through an iliac to the desired location within the aorta near the renal arteries. The catheter 20 carries the prosthesis 10 in a radially reduced configuration. At the targeted site, the catheter 20 releases the prosthesis 10, which expands radially into the position shown in Fig. 5.

A fastener assembly 34 is next deployed (which is shown generally in Fig. 5) to place fasteners 28 into the fastening region 26 of the trunk 12. The prosthesis 10 is thereby secured in position.

II. PROSTHESIS ATTACHMENT SYSTEMS AND METHODS

The fastener assembly 34 can be variously constructed and configured.

In an illustrated arrangement (see Fig. 6), the fastener attachment assembly 34 comprises a fastener guide component 36 and a fastener applier component 38. The guide component 36 can comprise, e.g., a guide sheath that desirably has a steerable or deflectable distal tip. The guide component 36 can be initially deployed over the guidewire that is used to deliver and position the prosthesis 10. The guide wire can be withdrawn after the guide component 36 is deployed and positioned, so that the applier component 38 can be introduced.

In this arrangement, the applier component 38 is desirably deployed through the guide component 36. A

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fastener drive mechanism 40 on the fastener applicator component 38 carries at least one fastener 28. The fastener drive mechanism 40 advances the fastener 28, causing it to penetrate the prosthesis 10 and underlying tissue wall. In this way, the fastener anchors the prosthesis 10 firmly in place.

In the illustrated embodiment (see Fig. 6), the fastener applicator 38 comprises a catheter 42. The catheter 42 carries the fastener drive mechanism 40 at its distal tip.

The fastener drive mechanism 40 comprises carrier 50. The carrier 50 is sized and configured to carry a selected fastener 28. The fastener drive mechanism 40 also includes a driver 52, which is coupled to impart movement to the carrier 50. The driver 52 and carrier 50 can comprise an integrated unit, with the carrier 50 being formed on the distal end of the driver 52, as shown, or they can comprise separate components, e.g., with the driver comprising a clutch or the like for the carrier 50. The driven movement deploys the fastener 28. The type of driven movement that is imparted depends upon the type of fastener 28 that is used.

In the illustrated embodiment (see Fig. 7) the fastener 28 comprises an open helical coil 54 with a sharpened leading tip 56. This type of helical fastener is deployed into tissue by rotational movement. Consequently, rotational movement is imparted by the driver 52 to the carrier 50, which is sized and configured to carry the fastener shown in Fig. 7.

The actuation of the driver 52 can, of course, be accomplished in various ways, e.g., mechanical (i.e., manual or hand-powered), electrical, hydraulic, or pneumatic.

In the illustrated embodiment (see Fig. 6), a drive motor 58 imparts rotation to the driver 52 through a

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drive cable 60. In the illustrated embodiment (Fig. 6), the drive motor 58 is housed in a handle 62, which is carried at the proximal end of the catheter 42. The drive cable 60 extends from the handle 62, through the catheter 42, and couples to the driver 52 at the distal end of the catheter 42. The drive cable 60 is desirably made of a suitable material that allows for both bending and rotation.

Activation of the drive motor 58 (e.g., by a physician controlled switch 64 on the handle 62) rotates, as a unit, the drive shaft 60, the driver 52, the carrier 50, and the fastener 28 in the carrier 50. The rotational movement causes the helical fastener 28 to travel into the prosthesis 10 and the tissue wall.

The implantation force of the fastener drive mechanism 40 is desirably resolved in some manner to provide positional stability and resist unintended movement of the carrier 50 relative to the implantation site. A resolution force is desirably applied to counteract and/or oppose the implantation force of the fastener drive mechanism 40. It is desirable to resolve some or all or a substantial portion of the implantation force within the vessel lumen (or other hollow body organ) itself, and preferably as close to the implantation site as possible.

The tubular body of the guide component 36 and/or the shaft of the catheter 42 can be sized and configured to possess sufficient column strength to resolve some or all or at least a portion of the implantation force within the vessel lumen or hollow body organ. Fig. 5 shows the guide component 36 braced against the vessel wall to apply a counterbalancing resolution force. In addition, or alternatively, the guide component 36 and/or the fastener applier component 38 can include some form of stabilization means for applying a counteracting force

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at or near the carrier 50. Various types of stabilization means are disclosed in co-pending United States Patent Application Serial Number 10/669,881, filed September 24, 2003, and entitled "Catheter-Based Fastener Implantation Apparatus and Methods with Implantation Force Resolution."

The carrier 50 itself can be various constructed, as can the fastener 28 to facilitate its coupling to the carrier 50. Representative embodiments will now be described.

A. Carriers with Independent Fastener Release Mechanisms

1. Carriers with Fastener Support Elements Having Release Mechanisms

The proximal end of the fastener 28 desirably includes a fitting 66 that, in use, couples the fastener 28 to the carrier 50. In one illustrated embodiment (see Fig. 7), the fitting 66 comprises an L-shaped brace or leg 66. The L-shape leg 66 desirably bisects the entire interior diameter of the coil 54; that is, the L-shaped leg 66 extends completely across the interior diameter of the coil 54, as Fig. 7 shows.

In this arrangement, the carrier 50 is sized and configured to engage the fitting 66, i.e., L-shaped leg 66, to thereby impart rotation to the helical fastener 28 to achieve implantation. The L-shaped leg 66 also serves as a stop to prevent the helical fastener 28 from penetrating too far into the tissue.

In one illustrated embodiment, the carrier 50 (see Figs. 8A(1) and 8A(2)) includes a fastener support element 68 that permits the selective release of the fastener 28. The support element 68 has at least two operating conditions.

In a first condition (see Fig. 8A(1)), the support element 68 engages the L-shaped leg 66 of the fastener 28

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to hold the fastener 28 on the carrier 50. In the first condition, rotation of the carrier 50 imparts rotation to the fastener 28 (as shown by the rotational arrow in Fig. 8A(2), to allow implantation of the fastener 28 into the prosthesis 10/tissue wall without releasing the fastener 28 (i.e., in response to rotation in one direction, as Fig. 8A(2) shows), as well as allow the withdrawal the fastener 28 from the prosthesis 10/tissue wall without releasing the fastener 28 (i.e., in response to rotation in an opposite direction, as Fig. 8C shows).

In a second condition (see Figs. 8B(1) and 8(B)(2)), the support element 68 releases the fastener 28. In the second condition, the fastener 28 and the carrier 50 can be separated. Release of the fastener 28 from the carrier 50 can be and desirably is accomplished without rotation of the carrier 50. It is desirable that the support element 68 can affect separation of the fastener 28 while the carrier 50 is stationary and not rotating.

The support element 68 therefore differentiates the step of operating the carrier 50 to implant the fastener 28 (by rotation of the carrier 50 with the support element 68 in its first condition) from the step of releasing the fastener 28 from the carrier 50 (by placing the support element 68 in its second condition, which is desirably achieved independent of rotation of the carrier 50). The support element 68 thereby also makes possible the use of the carrier 50 to withdraw the fastener 28 from tissue and to retrieve or reposition the fastener 28, if desired. Operation of the support element 68 independent of operation of the carrier 50 makes possible the release of the fastener 28 from the carrier 50 in a separate releasing step, which can be delayed to assure that implantation of the fastener 28 has been satisfactorily completed.

The features of the support element 68 just

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described can be achieved by the use of various structural embodiments. In the embodiment shown in Figs. 8A(1) and 8B(1), for example, the support element takes the form of hinged gripping jaws 70 on the distal end of the carrier 50. The gripping jaws 70 are moveable between a mutually closed condition (i.e., the first condition, as shown in Fig. 8A(1)) and a mutually opened condition (i.e., the second condition, as shown in Fig. 8B(1)). The L-shaped leg 66 of the fastener 28 is gripped by interference fit within a receptacle 72 formed between the jaws 70 when the jaws 70 are mutually closed, as Figs. 8A(1) and 8A(2) show. The receptacle 72 opens and frees the L-shaped leg 66 when the gripping jaws 70 are mutually opened, as Figs. 8B(1) and 8B(2) show.

In this embodiment, a physician-manipulated actuator 74 selectively pivots the hinged gripping jaws 70 from their mutually closed condition to their mutually opened condition. In the illustrated embodiment (see Figs. 8A(1) and 8B(1)), the actuator 74 comprises a pull cable 76 or stylet, which is coupled at its proximal end to a controller 78 on the handle (see Figs. 8A(2) and 8B(2)). The pull cable 76 extends through the catheter 42 and terminates at its distal end with a shaped cam element 78. The cam element 78 in the illustrated embodiment is ball-shaped. It occupies the area defined between tapered, facing cam surfaces 80 formed on the interior of the gripping jaws 70. When the jaws 70 are mutually closed (Fig. 8A(1)), the cam element 78 rests in the region of greatest distance between cam surfaces 80, adjacent the distal end of the gripping jaws 70. In this arrangement, when the physician manipulates the controller 78 to pull the cable 76 in an aft direction (i.e., toward the handle 62) (Fig. 8B), the cam element 78 travels on the tapered cam surfaces 80 toward the region of least distance between the surfaces 80. As it

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moves, the cam element 78 applies force against the cam surfaces 80 to pivot the jaws 70 open, i.e., moving them from the mutually closed to the mutually opened condition, as Fig. 8B(1) shows.

5 In the illustrated embodiment, the hinged gripping jaws 70 are desirably biased toward the mutually closed condition. A spring can be used for the purpose. Desirably, the gripping jaws 70 are formed by machining or molding from an elastic, spring-like material (metal
10 or plastic). The formed material includes an integral hinge 82, which normally biases the gripping jaws 70 closed. The hinge 82 yields to the force applied by the cam element 78 against the cam surfaces 80, but returns the jaws 70 to their mutually closed condition in the
15 absence of the force. In this arrangement (see Fig. 8A(1)), a physician can snap fit the L-shaped leg 66 of a fastener 28 into the receptacle 72 between the gripping jaws 70 at time of use. The snap fit provides tactile assurance that the fastener 28 has been properly engaged
20 within the receptacle 72 of the gripping jaws 70.

 In an alternative embodiment (see Figs. 9A(1) and 9B(1)), the support element 68 takes the form of spring-biased struts 84 on the carrier 50. The struts 84 resiliently open to accommodate snap-fit passage of the
25 L-shaped leg 66 into a retaining space 87 between the struts 84, allowing the coil 54 of the fastener 28 to nest upon the struts 84 (as Fig. 9A(2) shows). The resilient, normally closed condition of the struts 84 comprises the first operating condition, which holds the
30 fastener 28 on the struts 84, thereby securing the fastener 28 to the carrier 50. In this condition, rotation of the carrier 50 rotates the fastener 28, to allow implantation of the fastener 28 into tissue and/or withdrawal of the fastener 28 from tissue.

35 In this arrangement, a physician-manipulated

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actuator 86 comprising, e.g., a push cable or stylet, can be advanced forward through the catheter by operation of a controller 88 on the handle 62. The carrier 50 need not be and desirably is not rotated during this operation.

5 The push cable 86, when advanced (see Figs. 8B(1) and 8B(2)), contacts the L-shaped leg 66 and urges the leg 66 out of the retaining space 87 against the resiliently closed struts 84. The struts 84 are resiliently displaced by force of the L-shaped leg 66, which are caused to
10 assume a temporary, mutually opened condition. The fastener 28 can thereby be ejected from the carrier 50.

In an alternative arrangement (see Figs. 10A(1) and 10B(2)), the support element 68 may include normally open struts 90 that define a receptacle 92 and include a
15 detent 94 that governs passage of the L-shaped leg 66 into and out of the receptacle 92. A physician-manipulated actuator 96 comprising, e.g., a push-pull cable or stylet, can be advanced fore and aft through the catheter 42 into and out of contact with the detent 94,
20 e.g., by operation of a controller 98 on the handle 62 (see Figs. 10A(2) and 10(B)(2)). The cable 96, when advanced into contact with detent 94 (see Fig. 10A(1)(1)) locks the detent 94 in a position projecting into the receptacle 92. The detent 94, when locked, blocks entry
25 into or out of the receptacle 92. The cable 96, when withdrawn from contact with detent 94, unlocks the detent 94, and allows movement of the detent 94 out of the position blocking the receptacle 92.

The detent 94, when unlocked (see Figs. 10A(1) and
30 10A(2)), accommodates passage of the L-shaped leg 66 into the retainer 92 between the struts 90, while the remainder of the fastener 28 nests upon the struts 90. The fastener 28 can be loaded onto the carrier 50 in this fashion. The subsequent locking of the detent 94 (see
35 Fig. 10A(2)) blocks release of the L-shaped leg 66,

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securing the fastener 28 to the carrier 50. This corresponds to the above-described first operating condition. In this condition, rotation of the carrier 50 rotates the fastener 28 (as shown by the rotational arrow in Fig. 10A(2)), to allow implantation of the fastener 28 into the prosthesis 10/tissue wall and/or withdrawal of the fastener 28 from the prosthesis 10/tissue wall.

The cable 96, when advanced out of contact with detent 94, unlocks the detent 94 (see Figs. 10B(1) and 10B(2)). The carrier 50 need not be and desirable is not rotated during this operation. This allows passage of the L-shaped leg 66 past the detent 94 and free of the receptacle 92, as previously described, in response to aft movement of the catheter 42 and attached carrier 50.

Alternatively, as shown in Fig. 11, the detent 94 may be biased by a spring 100 toward a normally projecting condition to serve the same function.

2. Carriers With Releasable Fastener Cap Assemblies

In another illustrated embodiment (see Figs. 12A and 12B), the fastener 28 takes the form of a fastener cap assembly 102 that is releasably fitted onto a specially adapted carrier 104 (see Figs. 14A and 14B) at time of use. In the illustrated arrangement (see Figs. 12A and 12B), the fastener cap assembly 102 includes a helical fastener 106 on which a proximal cap 108 is mounted. The cap 108 can comprise a plastic, metal, or ceramic biocompatible material. The cap 108 can be secured to the proximal end of the fastener 106, e.g., by adhesives, machining, molding, or welding. The cap 108 includes preformed side mounts 110. In this arrangement, the cap 108 serves the same general function as the L-shaped leg 66 shown in Fig. 7, i.e., it is a fitting secured to the fastener that enables the coupling of the fastener 28 to the carrier.

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In this arrangement (see Figs. 14A and 14B), the carrier 104 includes an attachment mechanism 112, which will be described in greater detail later. The attachment mechanism 112 is sized and configured to engage the mounts 110, to thereby couple the fastener assembly 102 to the carrier 104 at time of use. The attachment mechanism 112 imparts rotation to the fastener assembly 102 when the carrier 104 is rotated (see Fig. 15A) to achieve implantation of the fastener assembly 102 into the prosthesis 10/tissue wall without releasing the fastener assembly 102 (i.e., in response to rotation of the carrier 104 in one direction, as Fig. 15A shows). The attachment mechanism 112 can also withdraw the fastener assembly 102 from the prosthesis 10/tissue wall (see Fig. 15C) without releasing the fastener assembly 102 (i.e., in response to rotation of the carrier 104 in an opposite direction, as Fig. 15C shows).

The carrier 104 also includes a release mechanism 114, as will be described in greater detail later. The release mechanism 114 selectively releases the fastener assembly 102 from the attachment mechanism 112 (see Fig. 15B). Release of the fastener assembly 102 from the attachment mechanism 112 can be and desirably is accomplished without rotation of the carrier 104.

The carrier 104 with an attachment mechanism 112 to which a fastener assembly 102 can be fitted at time of use, as well as an independent, selectively operable release mechanism 114 allows a physician to operate the carrier 104 to implant the fastener assembly 102 separate from the step of releasing the fastener assembly 102 after implantation has been accomplished. The carrier 104 with a selective release for the fastener assembly 102 also makes possible the withdrawal the fastener assembly 102 from tissue and the retrieval and/or reposition the fastener assembly 104, if desired, while the carrier 104

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remains secured to the fastener assembly 102. In this arrangement, release of the fastener assembly 102 from the carrier 104 can be accomplished once fastener assembly 102 has been satisfactorily implanted, or
5 otherwise at a time controlled by the operator.

The features of the carrier 104 as just described can be achieved by the use of various structural embodiments. In the embodiment shown in Figs. 13A and 13B, the attachment mechanism 112 comprises a pair of
10 gripper arms 116 coupled to the driver 52. The gripper arms 116 can be made by machining or molding from a metal or plastic material. The gripper arms 116 can be normally biased toward an inwardly deflected condition. The bias can be achieved, e.g., by imparting a spring memory to
15 the arms 116. Alternatively, the arms 116 need not be biased inwardly, but instead include outside edges that are inclined, as Fig. 13B shows. The arms include outwardly projecting tabs 126 that are sized to snap into mounts 110 on the cap 108 (as Fig. 14B shows).

20 In this arrangement, the release mechanism 114 comprises a spacer rod 118 extends between the gripper arms 116. The rod 118 carries at its distal end a cam element 120. When withdrawn from contact with the gripper arms 116 (as Fig. 13B shows), the gripper arms 116 are
25 positioned such that the tabs 126 will snap into the mounts 110 on the cap 108, as Fig. 14A shows. The cam element 120, when disposed in contact with the gripper arms 116 (as shown in Fig. 13A), spreads the gripper arms 116 apart, into an outwardly deflected condition, locking
30 the tabs 116 into the mounts 110, as Fig. 14B shows.

A spring 122 normally urges the cam element 120 toward contact with the gripper arms 116 (as shown in Figs. 13A and 14B). The rod 118, when pulled aft (as Figs. 13B and 14A show) withdraws the cam element 120,
35 and the gripper arms 116 are positioned to receive the

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cap 108. The rod 118 extends through the catheter 42 and is coupled to a controller 124 on the handle 62 (see Figs. 15A and 15B).

When the gripper arms 116 are maintained by the cam element 120 in their outwardly deflected condition (see Fig. 14B), the tabs 126 lock into the mounts 110 on the fastener cap 108, securing the fastener assembly 102 to the carrier 104. Conversely, when the cam element 120 is withdrawn, the tabs 126 allow the fastener assembly 102 to be inserted onto or separated from the carrier 104.

In use, the physician pulls back on the control 124 to withdraw the cam element 120 against the bias of the spring 122 and snap-fits a fastener assembly 102 onto the carrier 104. The physician then releases the control 124 to allow the spring 122 to return forward and lock the fastener assembly 102 onto the carrier 104. The physician then deploys the catheter 42 holding the fastener assembly 102 to the targeted site (see Fig. 15A). By rotating the carrier 104, the physician implants the fastener assembly 102 into the prosthesis 10/tissue wall.

When the fastener assembly 102 has been satisfactorily implanted, the physician pulls back on the control 124 and the catheter 42 (see Fig. 15B) to separate the fastener assembly 102 from the carrier 104. The physician withdraws the catheter 42 and repeats the forgoing steps until the desired number of fastener assemblies 102 has been implanted.

B. Carriers with Two-Phase Ejection of Fasteners

The above-described embodiments provide the ability to withdraw a given fastener from a prosthesis/tissue wall prior to completion of the implantation step. The above-described embodiments make this feature possible by providing a fastener applicator 38 that includes a fastener release mechanism that works independent of the fastener implantation mechanism.

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In Figs. 16A(1)/A(2), 16B, and 16C, a fastener applicator 38 includes a fastener carrier 128 that implements this feature without an independent release mechanism. In Figs. 16A(1)/A(2), 16B, and 16C, the fastener carrier 128 is operated in two phases. The first or initial phase advances a fastener 28 into an incomplete implantation position within a prosthesis 10/tissue wall (Fig. 16B), which represents a sufficient distance to gain purchase, but which is short of full implantation. That is, given that full implantation of the fastener 28 requires the application of an implantation force under prescribed conditions, i.e., for a prescribed time period or for a prescribed number of rotations of the fastener-- the implantation force is applied to the fastener 28 during the first phase under conditions that do not achieve the prescribed conditions. Thus, full implantation is not achieved. During the first phase, the fastener 28 remains coupled to the fastener carrier 128, to allow the physician to operate the fastener carrier 128 to withdraw/retrieve the fastener 28, if desired (see Fig. 16D).

The first phase presents a decision point to the physician. At end of the first phase, a lull phase exists, during which operation of the fastener carrier 128 is interrupted. A prescribed input command is required to move out of the lull phase. During the lull phase, the physician can elect to withdraw or retrieve the fastener 28 (Fig. 16D). Alternatively, the physician can elect to continue implantation and proceed to the second phase. In the second or final phase, the fastener carrier 128 advances the fastener 28 from the incomplete implantation position (Fig. 16B) to the complete implantation position (Fig. 16C), at the end of which the fastener 28 itself automatically separates from the fastener carrier 128. That is, during the second phase,

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implantation force is applied to the fastener 28 under conditions that supplement the conditions of the first phase in order to meet the conditions prescribed for full implantation.

5 The fastener applier 38 can implement this feature in various structural embodiments. In the illustrative embodiment shown in Fig. 16A(1), the carrier 128, coupled to a driver 52, includes a slot 130, which receives the L-shaped leg 66 to couple the fastener 28 for rotation
10 with the carrier 128. In this embodiment, the turns of the coil 54 rest in complementary internal grooves 132 that surround the carrier 128. The grooves 132 could be positioned along the entire length of the fastener 28 or within a portion of its length. Activation of the drive
15 mechanism rotates, as a unit, the driver 52, the carrier 128, and the helical fastener 28 (as Fig. 16A(2) shows). This rotation causes the helical fastener 28 to travel within the internal grooves 132 of the fastener applier and into the prosthesis 10 and tissue wall. Uninterrupted
20 rotation of the carrier 128 will cause the helical fastener 28 to be rotated completely off the carrier and through the prosthesis 10 and into the tissue wall (as Fig. 16C shows).

 In the illustrated embodiment, the drive mechanism
25 includes a motor control unit 134 (see Figs. 16A(2), 16B, and 16D). The motor control unit 134 is conditioned to operate the carrier 128 in the two distinct phases, as above described. The first phase of fastener implantation is initiated by the physician activating a rotation
30 command, e.g., by manipulating a first switch 136 on the handle 62. During the first phase of deployment (Fig. 16B), the carrier 128 is driven sufficient to rotate the helical fastener 28 to a position in which the distal portion of the fastener 28 has implanted itself into the
35 target tissue, but in which the proximal portion of the

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fastener 28 is still retained within the internal threads 132 of the carrier 128. At this point, the first phase ends, and the motor control unit 134 enters the lull phase, automatically interrupting rotation of the carrier 128. The motor control unit 134 can accomplish motor control in this fashion by either conventional mechanical and or electronic means, e.g., through a programmable microprocessor.

At this juncture, the physician has the option of reversing the insertion process and removing the fastener 28, if desired (see Fig. 16D), e.g., by reversing the switch 136 or activating another switch 138 on the handle 62. At this juncture, the physician also has the option of completing the implantation process, e.g., by manipulating the switch 136 in a preprogrammed fashion (for example, by double switching).

In one variation, the motor control unit 136 can receive input reflecting a performance criteria measured during the first phase of deployment. The motor control unit 136 assesses the value of the performance criteria, to determine whether it falls within a predetermined acceptable range. If so, the second phase of deployment may occur automatically without a pause and without a second input from the user. For example, motor current used during the first phase of fastener deployment could be measured, and from this the fastener driving torque could be calculated. A torque within a range of acceptable values would imply that the fastener 28 had successfully entered the target tissue and fastener implantation could be completed automatically. A torque that was outside the acceptable range could result in either a pause at the end of phase one, where the user could make the decision to continue or reverse the fastener deployment, or an automatic reversal of fastener deployment.

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In an alternative embodiment, a fastener release mechanism 114 of the type shown, e.g., in Figs. 13A/B and 14A/B can be used in association with a motor control unit 134. In this arrangement, the motor control unit 134 is conditioned to operate the carrier 104 to drive the fastener assembly 102 in a single phase of deployment into tissue. At this point, the release mechanism 114 can be operated in the manner previously described, to separate the fastener assembly 102 from the carrier 104. The motor control unit 134 can be conditioned by mechanical and/or electronic means to indicate and/or control the number of revolutions and/or the torque applied to accomplish the installation of the fastener assembly 102 in tissue. In this embodiment, there is no need for multiple phases, because the physician ultimately controls the release of the fastener assembly 102 by manipulation of the release mechanism 114.

C. Carriers with Tethered Fasteners

In all of the above embodiments, or as an alternative embodiment in and of itself, a fastener applier 38 can include an element 140 to releasably tether a fastener 28 to the applier 38 even after the fastener 28 has been separated from the applier 38 (see Fig. 17A). The tether element 140 serves as a "life line," maintaining a connection of last resort between the applier 38 and a fastener 28. The tether element 28 allows the fastener 28 to be retrieved if, for any reason, the fastener 28 inadvertently breaks loose from tissue and/or the applier 38 during or after implantation. The connection between the tether element 140 and the applier 38 requires a deliberate act of the physician to be broken, adding a confirming, final step to the implantation process (see Fig. 17B).

The tether element 140 can be variously constructed. In Fig. 17A, the tether element 140 comprises a thread,

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braid, wire, or tubing structure 142. The proximal end of the tether element structure 142 is attached to the fastener applicator 38 in a manner that can be detached by application of a deliberate pulling force. The distal end
5 of the tether element structure 142 is frangible and can be broken by a force less than the deliberate pulling force once desired deployment of the fastener 28 is confirmed, as Fig. 17B shows. The tether element structure 142 has sufficient length to be able to retract
10 the fastener applicator 38 enough to visualize the fastener in position (as Fig. 17A shows). The force to break the frangible distal end of the tether element structure 142 is less than the force required to dislodge the fastener 28 from tissue. Desirably, the frangible distal end of
15 the tether element structure 142 detaches from the fastener 28 without leaving remnants on the fastener 28 (as Fig. 17B shows).

The tether element structure 142 can be sized and configured in other, different ways to form a frangible
20 connection with a fastener 28. For example (see Figs. 18A and 18B), the L-shaped leg 66 could be crimped to form an area of weakness 144 (Fig. 18A), to which the tether element structure 142 applies force to free the tether element structure 142 from the fastener 28 (Fig. 18B).

25 Alternatively, the junction between the tether element structure 142 and the fastener 28 can comprise an area of weakness 146 (e.g., by welding, soldering, gluing, heating, or shearing) that is broken by the application of a prescribed force in a prescribed manner,
30 e.g., by rotation (Fig. 19A) or pulling (Fig. 19B). Alternatively, the junction between the tether element structure 142 and the fastener 28 may comprise a threaded joint 146 (see Figs. 20A and 20B); or a snap-fit ball and socket joint 148 (see Figs. 21A and 21B); or a slide-fit
35 joint 150 (see Figs. 22A and 22B); or a knotted joint

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152 (Figs. 23A and 23B); or a frictional junction 154 that
is relieved by split open a tube 156 using a rip cord 158
(Figs. 24A and 24B). Still, alternatively, the junction
between the tether element 140 and the fastener 28 can
5 comprise an interlocking mechanism 160, for example, a
slidable outer sleeve 162 that, when advanced (Fig. 25A),
captures an appendage 164 on the fastener 28 and, when
retracted (Fig. 25B), frees the appendage 164.

The preferred embodiments of the invention are
10 described above in detail for the purpose of setting
forth a complete disclosure and for the sake of
explanation and clarity. Those skilled in the art will
envision other modifications within the scope and spirit
of the present disclosure.

15 The above described embodiments of this invention
are merely descriptive of its principles and are not to
be limited. The scope of this invention instead shall be
determined from the scope of the following claims,
including their equivalents.

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We Claim:

1. A tool for applying an implantation force to a fastener sized and configured for implantation in tissue in response to an implantation force, the tool
5 comprising
a tool body,
a driven member carried by the tool body and being operable to apply the implantation force, the driven member including a drive actuator to operate the
10 driven member, and
a mechanism on the driven member operable in a first condition to couple the fastener to the driven member to transfer the implantation force from the driven member to the fastener, the mechanism being operable in a
15 second condition to release the fastener from the driven member, the mechanism including a second actuator operable independent of the drive actuator to place the mechanism in the second condition.
2. An assembly according to claim 1
20 wherein the second actuator also places the mechanism in the first condition.
3. An assembly according to claim 1
wherein the mechanism includes means for placing the mechanism in the first condition absent
25 operation of the second actuator.
4. An assembly according to claim 1
wherein the mechanism includes a support element on the driven member sized and configured to assume the first condition absent operation of the second
30 actuator.
5. An assembly according to claim 1
wherein the driven member is also operable to apply a removal force to withdraw the fastener from tissue, and
35 wherein the mechanism is also operable in the

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first condition to couple the fastener to the driven member to transfer the removal force from the driven member to the fastener.

5 6. An assembly according to claim 5
 wherein the driven member is rotated in one direction to apply the implantation force and rotated in an opposite direction to apply the removal force.

 7. An assembly according to claim 1
 wherein the tool body includes a tube.

10 8. An assembly according to claim 1
 wherein the mechanism includes a support element on the driven member that defines a receptacle that, in the first condition, is closed to retain at least a portion of the fastener and that, in the second
15 condition, is opened to release the fastener, and
 wherein the second actuator opens the receptacle.

 9. An assembly according to claim 8
 wherein the second actuator also closes the
20 receptacle.

 10. An assembly according to claim 8
 wherein the support element includes a bias that normally closes the receptacle, and
 wherein the second actuator overcomes the bias
25 to open the receptacle.

 11. An assembly according to claim 8
 wherein the support element includes a bias that normally closes the receptacle, and
 wherein the second actuator ejects the
30 fastener from the receptacle, overcoming the bias.

 12. An assembly according to claim 8
 wherein the support element includes a detent associated with the receptacle that, in the first condition, is advanced to project into the receptacle to
35 close the receptacle and that, in the second condition,

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is withdrawn from the receptacle to open the receptacle,
and

wherein the second actuator withdraws the
detent to open the receptacle.

5 13. An assembly according to claim 12
 wherein the second actuator also advances the
detent to close the receptacle.

 14. An assembly according to claim 8
 wherein the support element includes a detent
10 associated with the receptacle that, in the first
condition, is advanced to project into the receptacle to
close the receptacle and that, in the second condition,
is withdrawn from the receptacle to open the receptacle,
the support element including a bias that normally
15 advances the detent, and

 wherein the second actuator overcomes the bias
by ejecting the fastener past the detent.

 15. An assembly according to claim 8
 wherein the support element comprises a jaw
20 assembly that defines the receptacle.

 16. An assembly according to claim 8
 wherein the support element comprises a strut
assembly that defines the receptacle.

 17. An assembly according to claim 1
25 wherein the mechanism includes a support
element on the driven member that defines a gripping
assembly that, in the first condition, is advanced to
engage at least a portion of the fastener and that, in
the second condition, is withdrawn to disengage the
30 fastener, and

 wherein the second actuator withdraws the
gripping assembly to disengage the fastener.

 18. An assembly according to claim 17
 wherein the support element includes a bias
35 that normally advances the gripping assembly, and

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wherein the second actuator overcomes the bias to withdraw the gripping assembly.

19. An assembly according to claim 1 further including a fitting sized and
5 configured to be appended to the fastener, and wherein the mechanism is sized and configured to engage the fitting when in the first condition and to disengage the fitting when in the second condition.

20. An assembly according to claim 19
10 wherein the fitting includes a brace sized and configured to be carried on a proximal end of the fastener.

21. An assembly according to claim 19 wherein the fitting includes a cap sized and
15 configured to be carried on a proximal end of the fastener.

22. An assembly according to claim 1 further including an element tethering the fastener to the tool body, the element including a
20 frangible portion.

23. An assembly according to claim 1 wherein the driven member is rotated to apply the implantation force.

24. An assembly according to claim 1 further including a controller coupled to the driven member to operate the driven member to apply a
25 prescribed implantation force.

25. A system for implanting a fastener in tissue comprising
30 a fastener sized and configured for implantation in tissue in response to an implantation force, including a shaped fitting carried by the fastener, and

a fastening tool including a driven member
35 operable to apply the implantation force, the driven

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member including a drive actuator to operate the driven member, a mechanism on the driven member operable in a first condition to engage the shaped fitting and couple the fastener to the driven member to transfer the implantation force from the driven member to the fastener, the mechanism being operable in a second condition to disengage the shaped fitting and release the fastener from the driven member, the mechanism including a second actuator operable independent of the drive actuator to place the mechanism in the second condition.

26. A system according to claim 25

wherein the driven member is also operable to apply a removal force to withdraw the fastener from tissue, and

wherein the mechanism is also operable in the first condition to engage the shaped fitting and couple the fastener to the driven member to transfer the removal force from the driven member to the fastener.

27. A system according to claim 26

wherein the driven member is rotated in one direction to apply the implantation force and rotated in an opposite direction to apply the removal force.

28. A system according to claim 25

further including an element tethering the fastener to the fastening tool, the element including a frangible portion.

29. A system according to claim 25

wherein the fastening tool includes a tube that carries the driven member.

30. A system according to claim 25

wherein the driven member is rotated to apply the implantation force.

31. An assembly according to claim 25

further including a controller coupled to the driven member to operate the driven member to apply a

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prescribed implantation force.

32. A tool for applying an implantation force to a fastener sized and configured for implantation in tissue in response to an implantation force applied according to prescribed conditions, the tool comprising
5 a tool body,
a driven member carried by the tool body and being operable to apply the implantation force,
a mechanism on the driven member to couple the
10 fastener to the driven member to transfer the implantation force from the driven member to the fastener,
a controller coupled to the driven member, the controller including an initial phase operating the
15 driven member to apply the implantation force under conditions than are short of the prescribed conditions, a lull phase commencing at the end of the initial phase interrupting operation of the driven member, a final phase operating the driven member under conditions that
20 supplement the conditions of the initial phase to achieve the prescribed conditions, the controller requiring, after the initial phase, a prescribed command to advance from the lull phase to the final phase.

33. An assembly according to claim 32
25 wherein the prescribed command is based, at least in part, upon input from an operator.

34. An assembly according to claim 32
wherein the prescribed command is based, at least in part, upon input reflecting a sensed operating
30 condition.

35. An assembly according to claim 32
wherein the driven member is also operable to apply a removal force to withdraw the fastener from tissue, and
35 wherein the controller includes a removal

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phase operating the driven member to apply the removal force, the controller requiring, after the initial phase, a different prescribed command to advance from the lull phase to the removal phase.

5 36. An assembly according to claim 35
 wherein the driven member is rotated in one direction to apply the implantation force and rotated in an opposite direction to apply the removal force.

10 37. An assembly according to claim 32
 further including an element tethering the fastener to the tool body, the element including a frangible portion.

15 38. An assembly according to claim 32
 wherein the tool body includes a tube that carries the driven member.

 39. An assembly according to claim 32
 wherein the driven member is rotated to apply the implantation force.

20 40. A tool for applying an implantation force to a fastener sized and configured for implantation in tissue in response to an implantation force, the tool comprising

 a tool body,
 a driven member carried by the tool body and
25 being operable to apply the implantation force, and
 an element tethering the fastener to the tool body, the element including a frangible portion.

 41. An assembly according to claim 40
 wherein the tool body includes a tube that
30 carries the driven member.

 42. An assembly according to claim 40
 further including a controller coupled to the driven member to operate the driven member to apply a prescribed implantation force.

35 43. A method for implanting a fastener in

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tissue comprising the steps of

providing a tool as defined in claim 1,
coupling a fastener to the driven member when
the mechanism is in the first condition,
5 accessing a tissue region,
operating the drive actuator to implant the
fastener in the tissue region, and
operating the second actuator to release the
fastener from the driven member.

10 44. A method for implanting a fastener in
tissue comprising the steps of
providing a tool as defined in claim 32,
coupling a fastener to the driven member,
accessing a tissue region,
15 operating the driven member during the initial
phase to partially implant the fastener in the tissue
region,
deciding during the lull phase to commence the
final phase,
20 entering the prescribed command to advance
from the lull phase to the final phase, thereby
completing the implantation of the fastener in the tissue
region.

25 45. A method for implanting a fastener in
tissue comprising the steps of
providing a tool as defined in claim 32,
coupling a fastener to the driven member,
accessing a tissue region,
operating the driven member during the initial
30 phase to partially implant the fastener in the tissue
region,
deciding during the lull phase not to commence
the final phase,
deciding during the lull phase to remove the
35 fastener and thereby fail to enter the prescribed command

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so as not to advance from the lull phase to the final phase.

46. A method for implanting a fastener in tissue comprising using a tool as defined in claim 40.

5 47. A method for implanting a fastener in tissue comprising the steps of

providing a tool as defined in claim 40,
coupling a fastener to the driven member,
accessing a tissue region,

10 operating the driven member during the initial phase to implant the fastener in the tissue region, and
breaking the frangible portion of the tethering element to part the fastener from the tool.

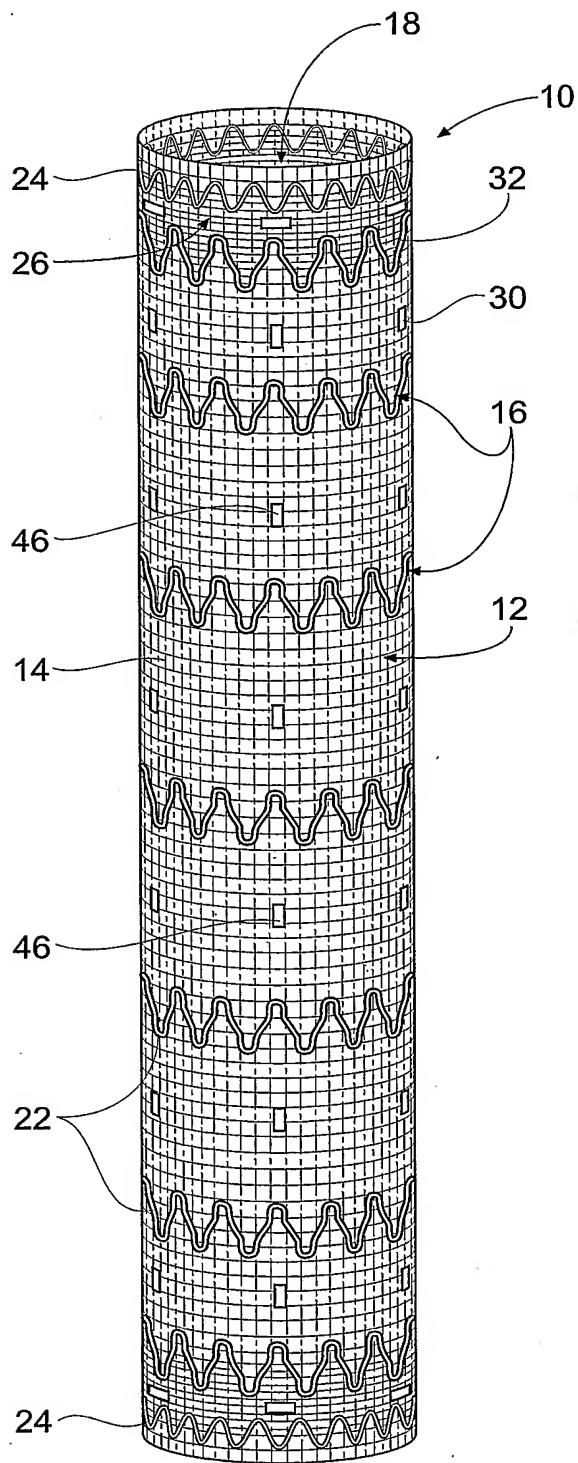


Fig. 1

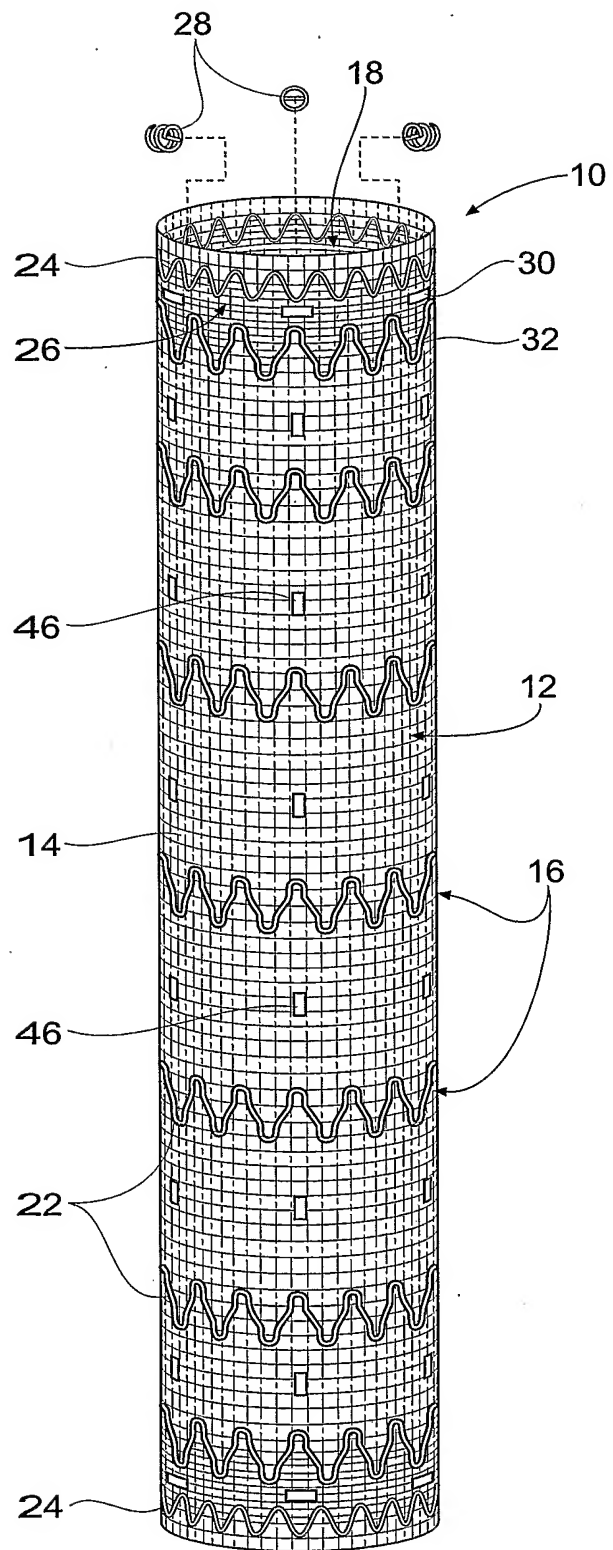


Fig. 2

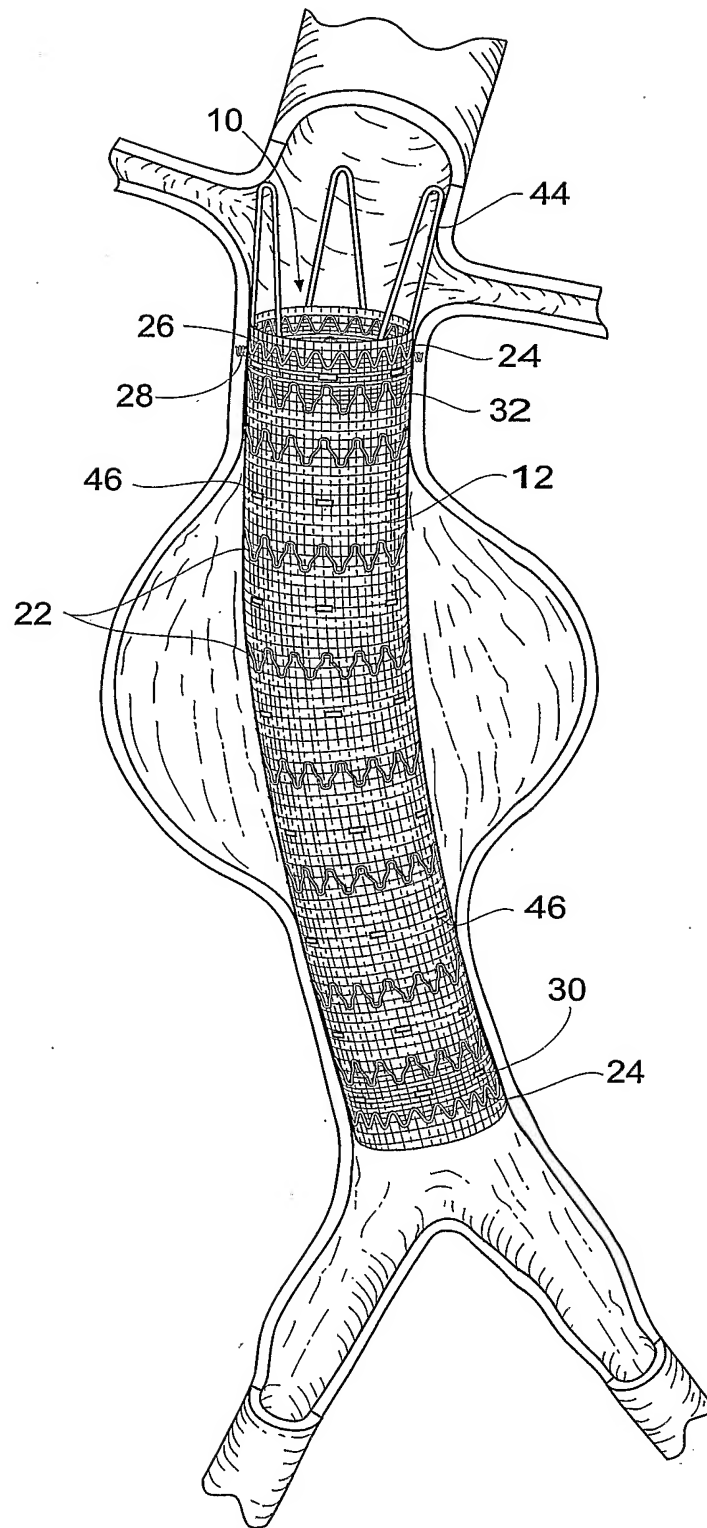


Fig. 3

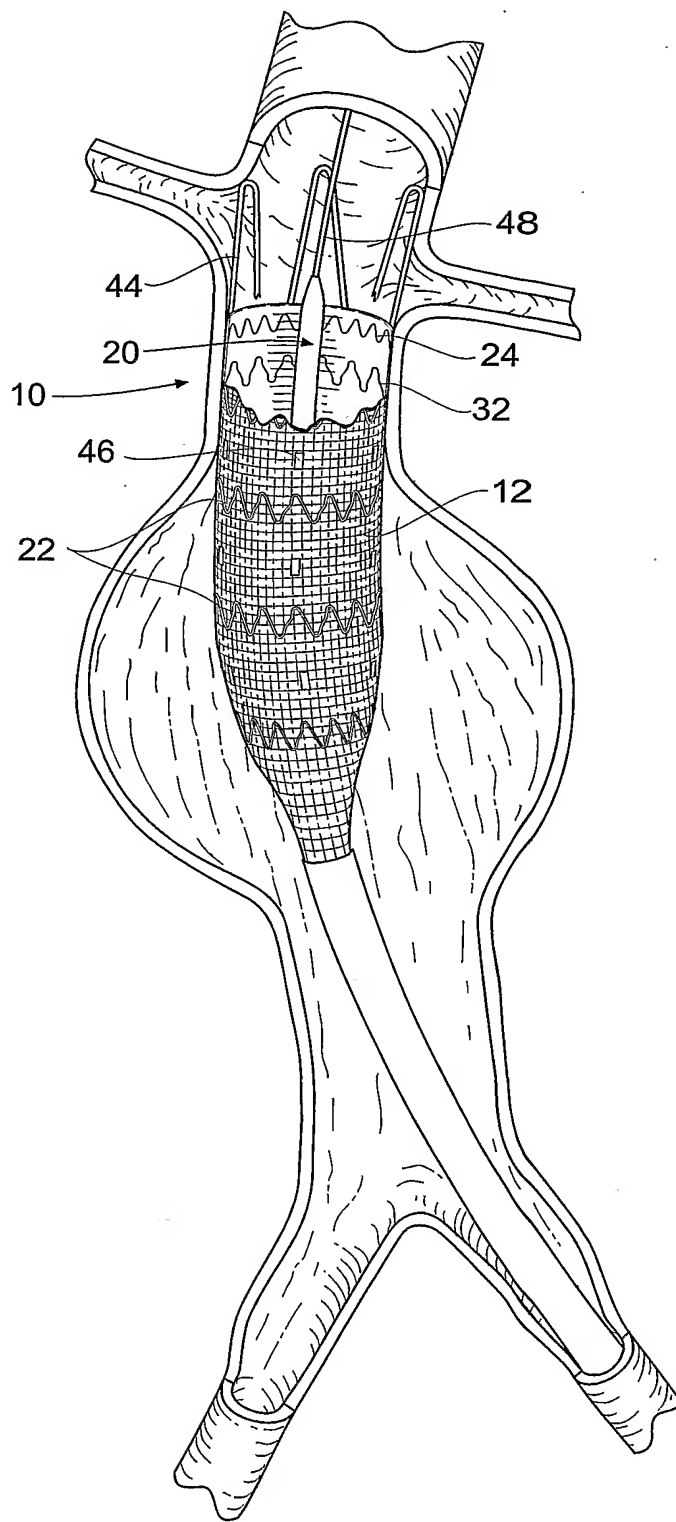
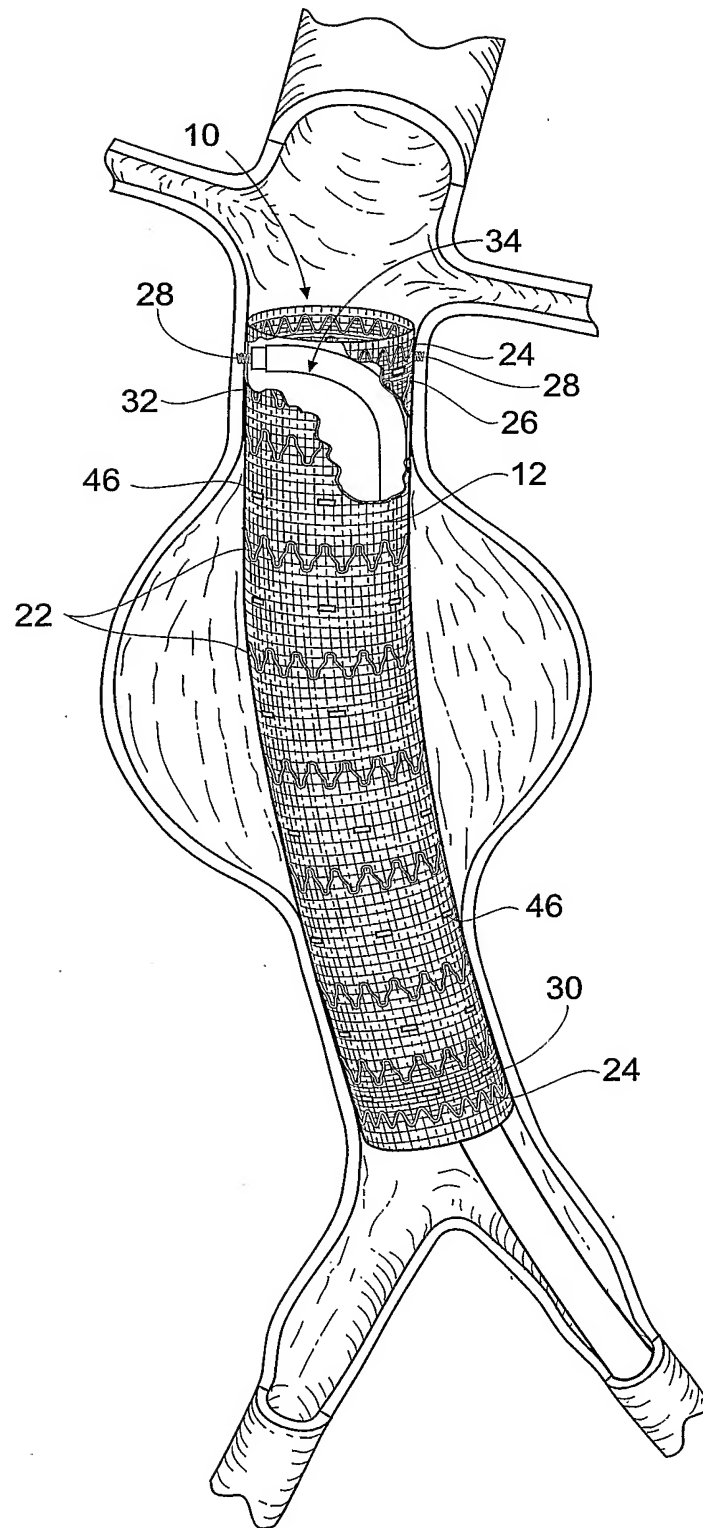


Fig. 4

*Fig. 5*

5/25

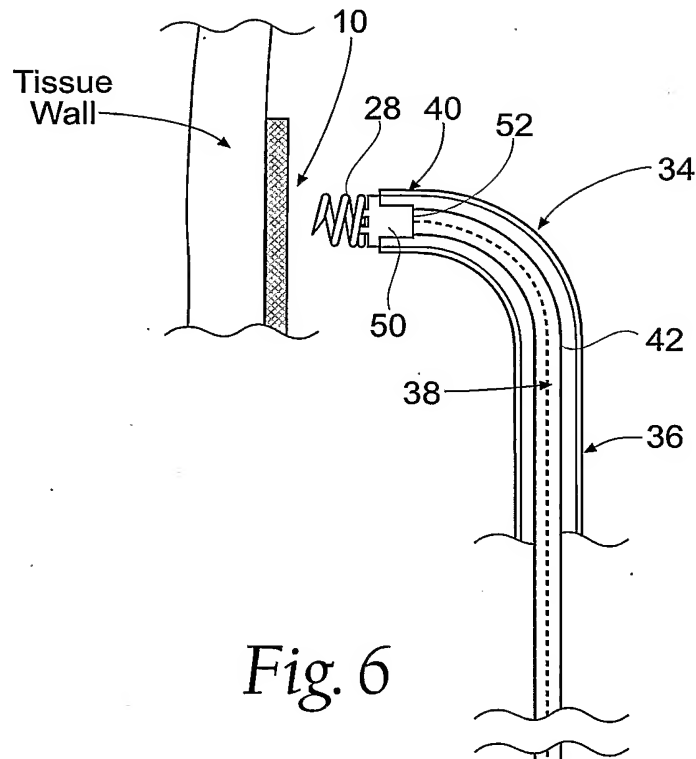


Fig. 6

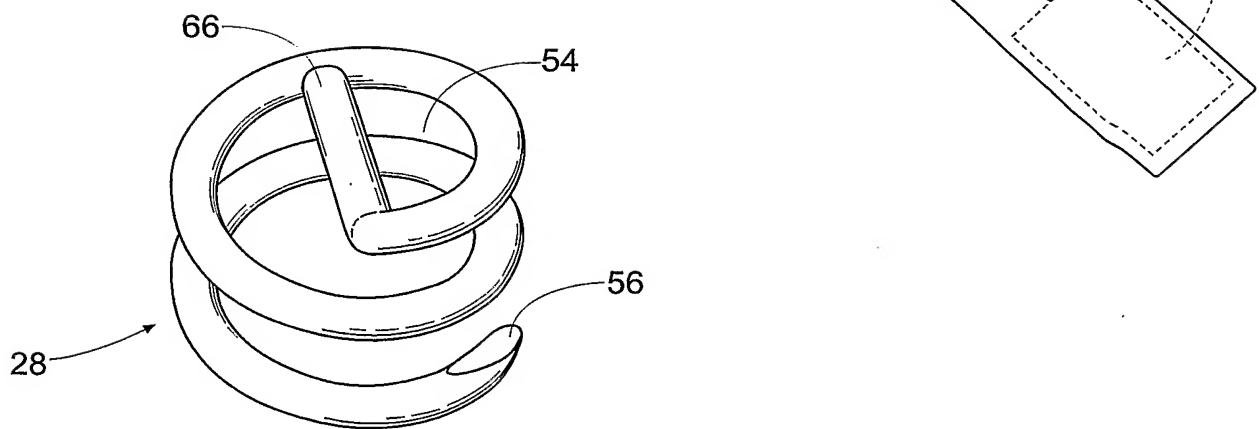
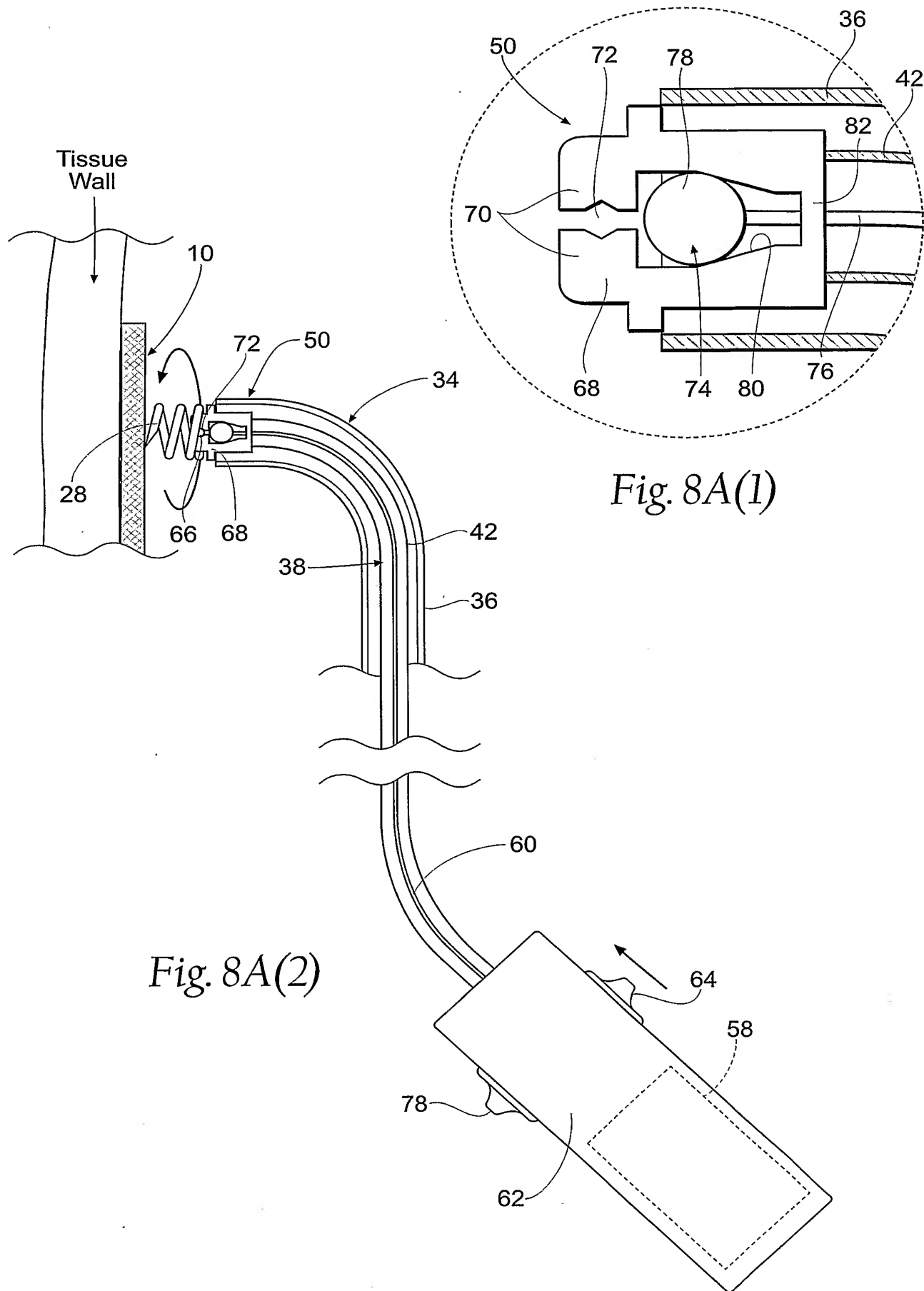


Fig. 7



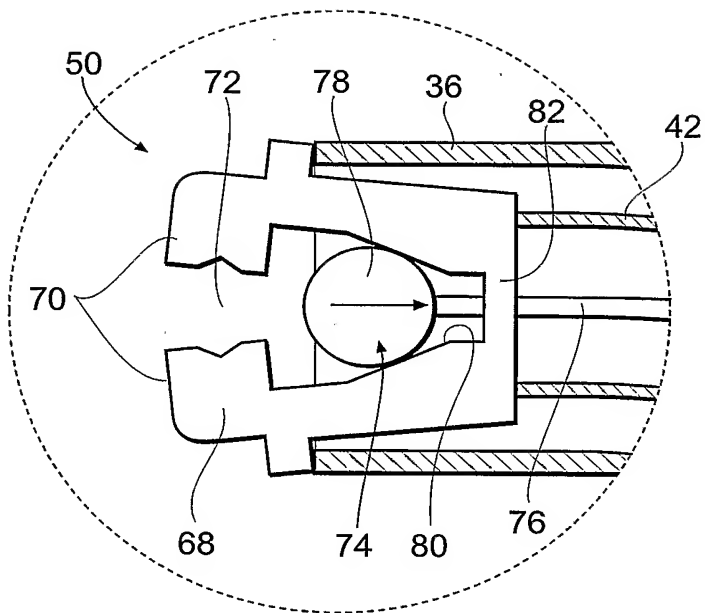


Fig. 8B(1)

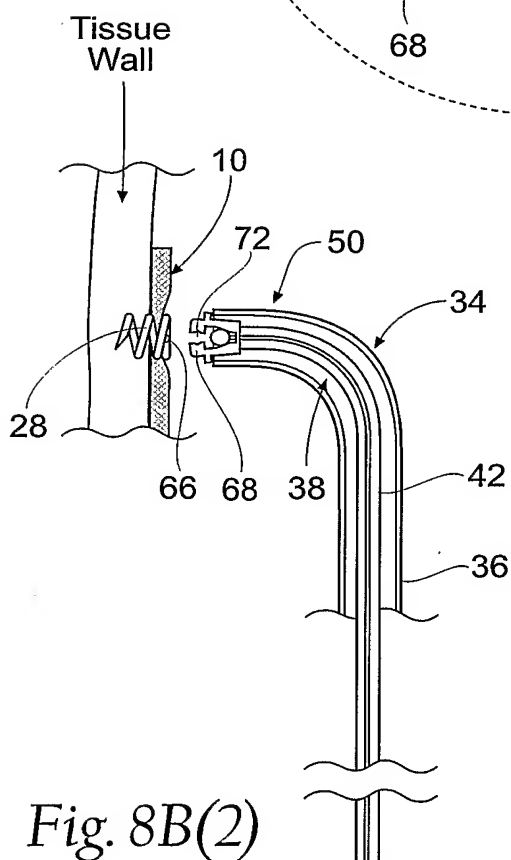


Fig. 8B(2)

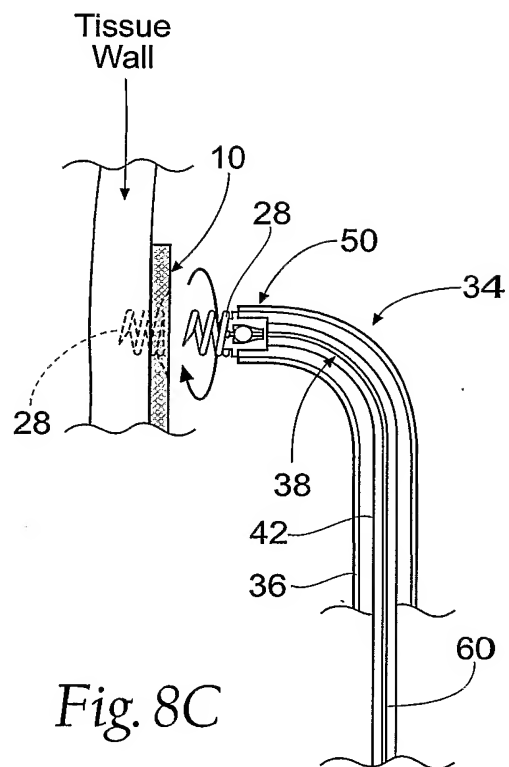
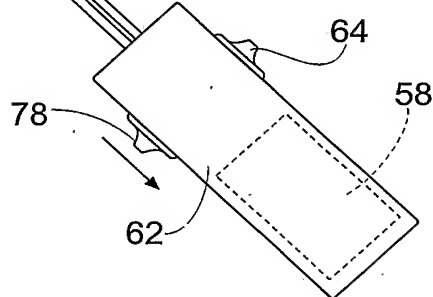
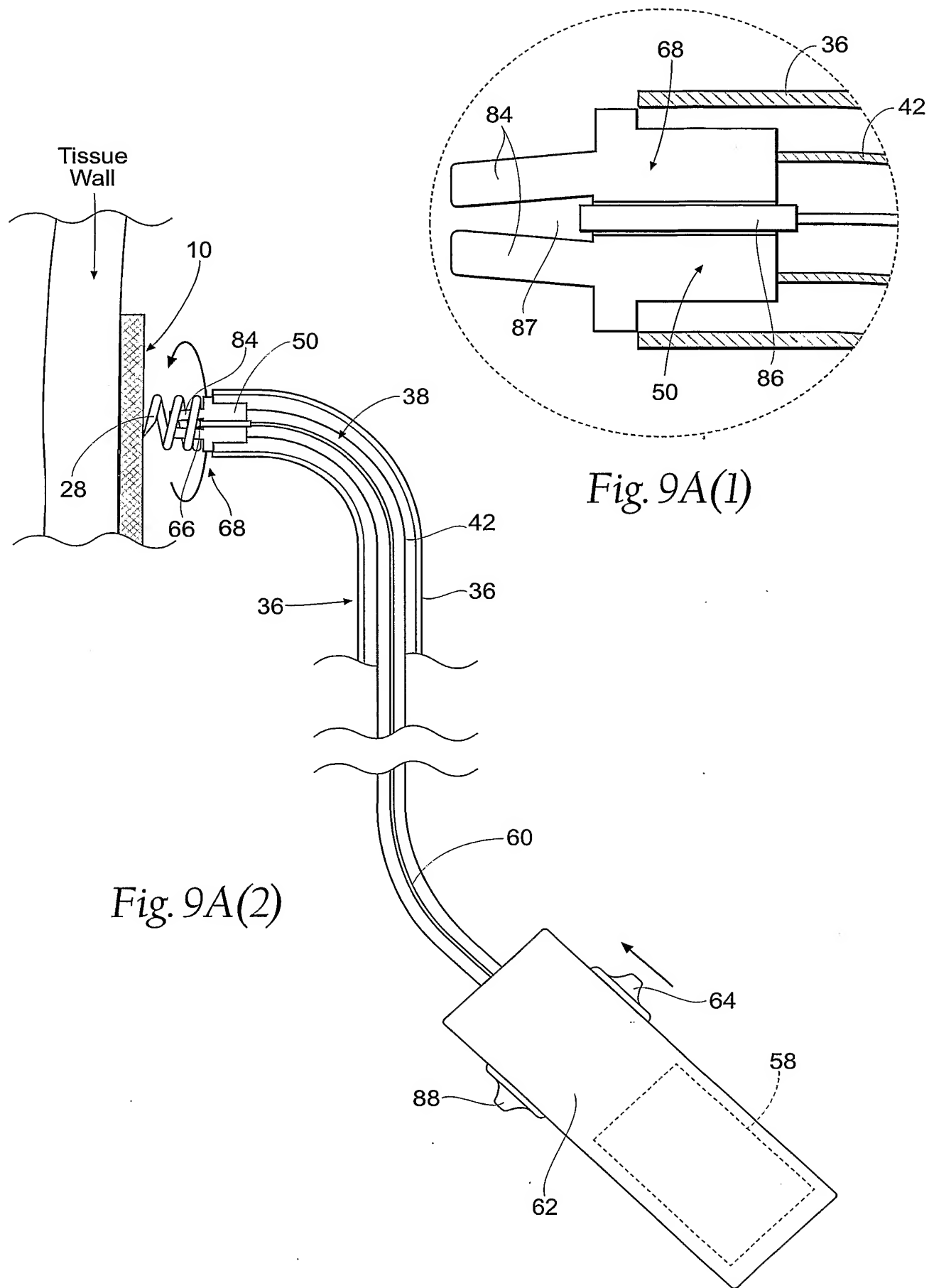


Fig. 8C





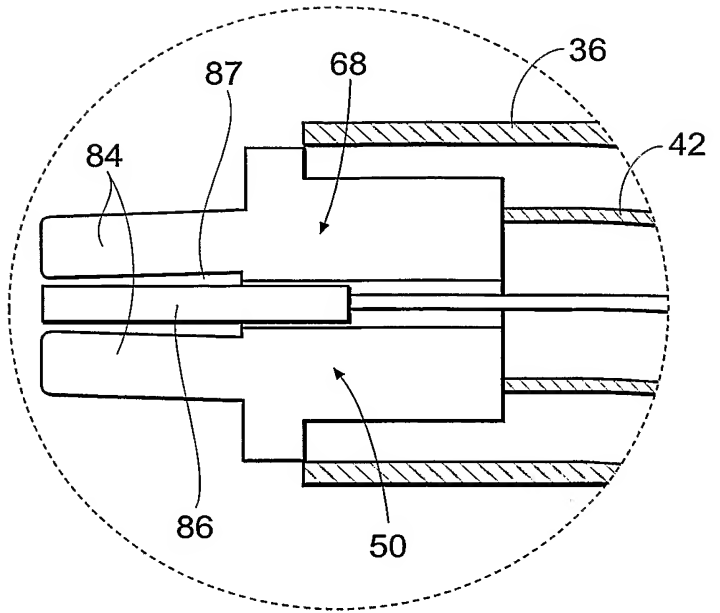
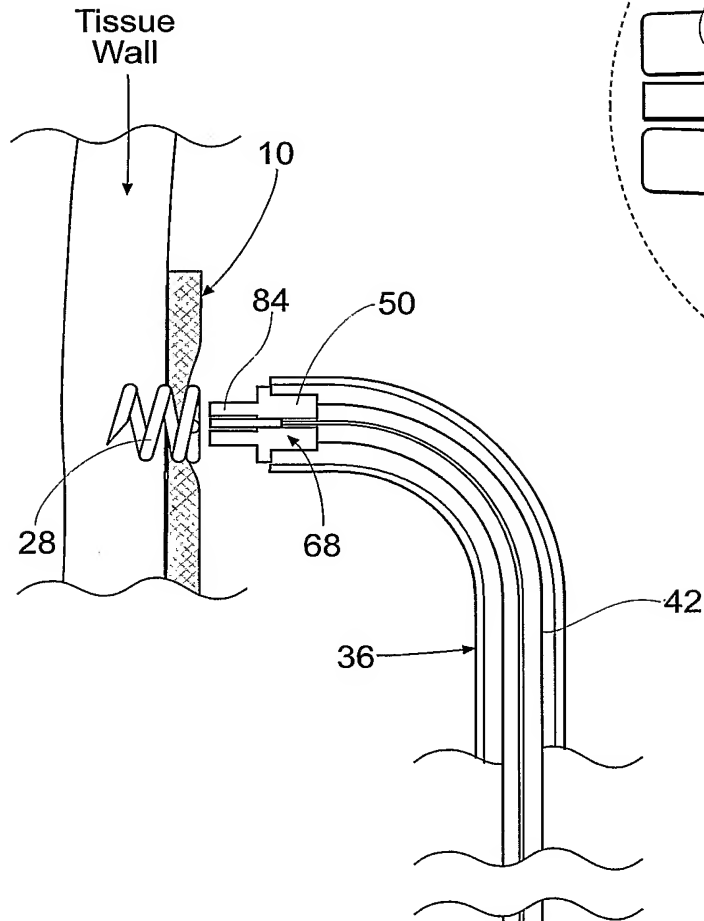


Fig. 9B(1)

Fig. 9B(2)

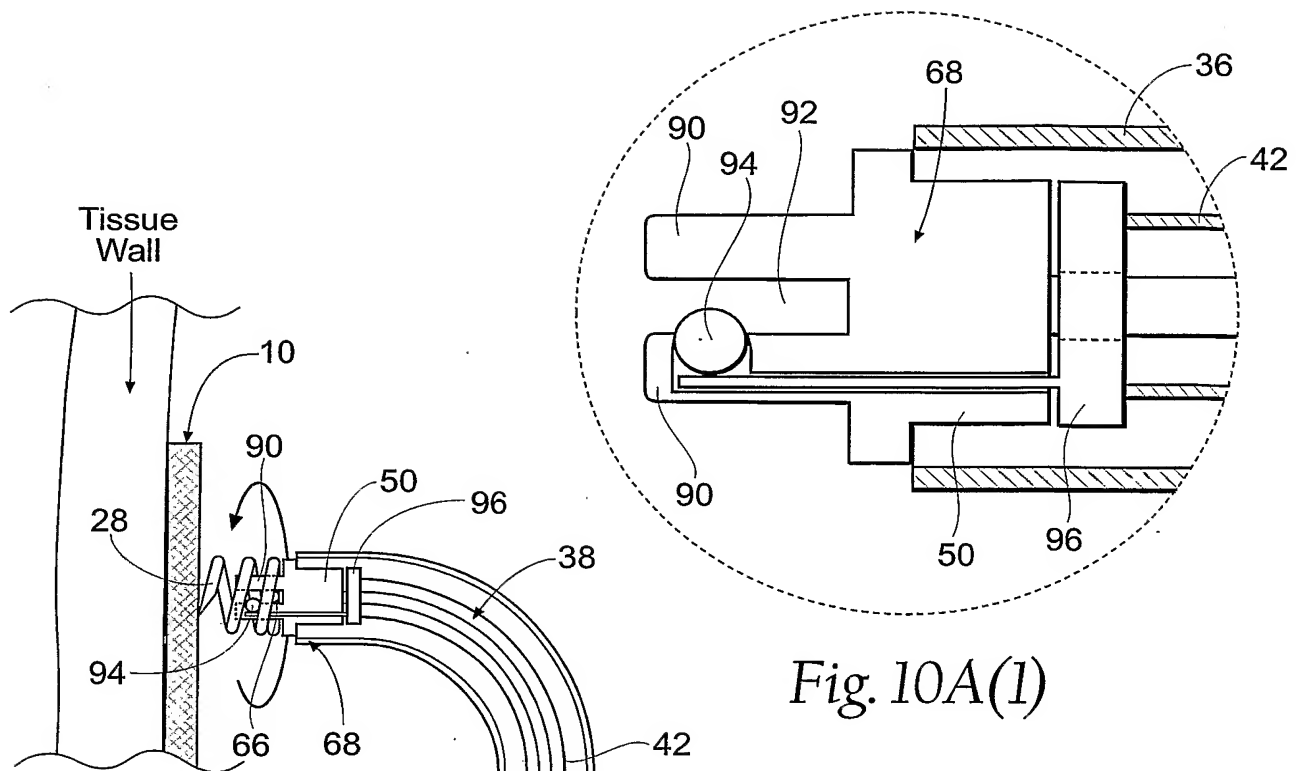
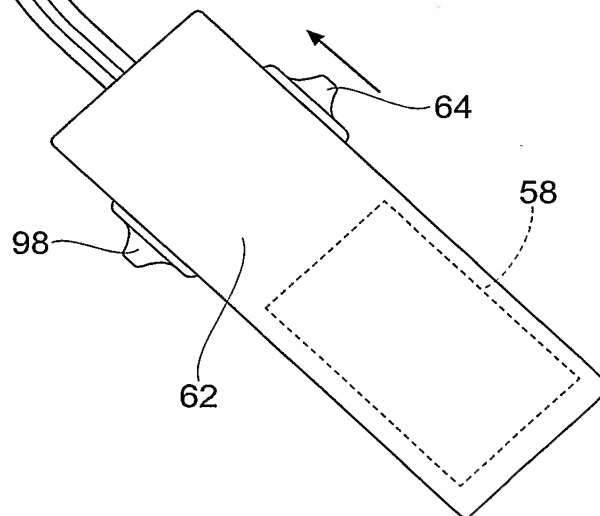
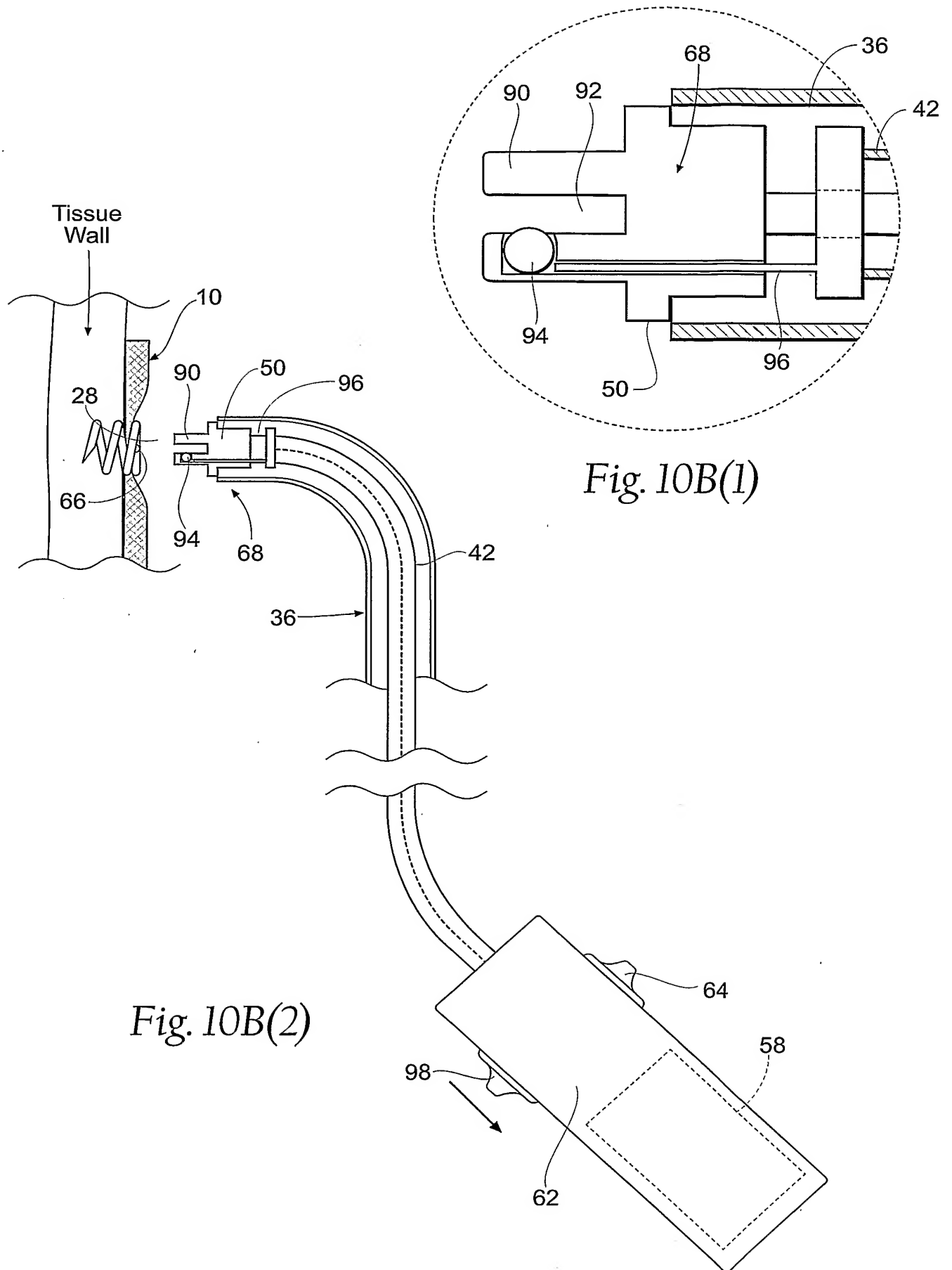
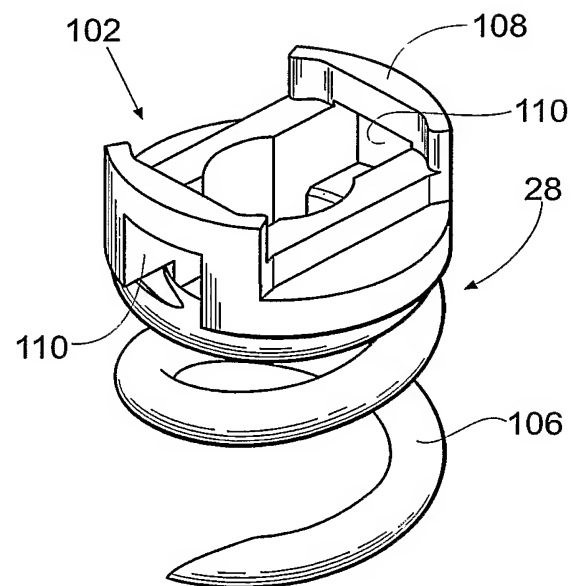
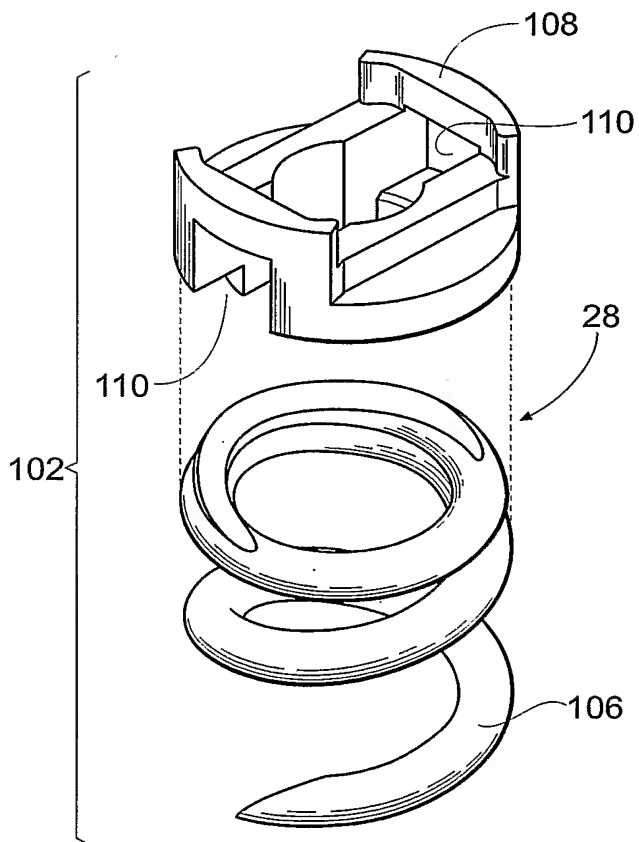
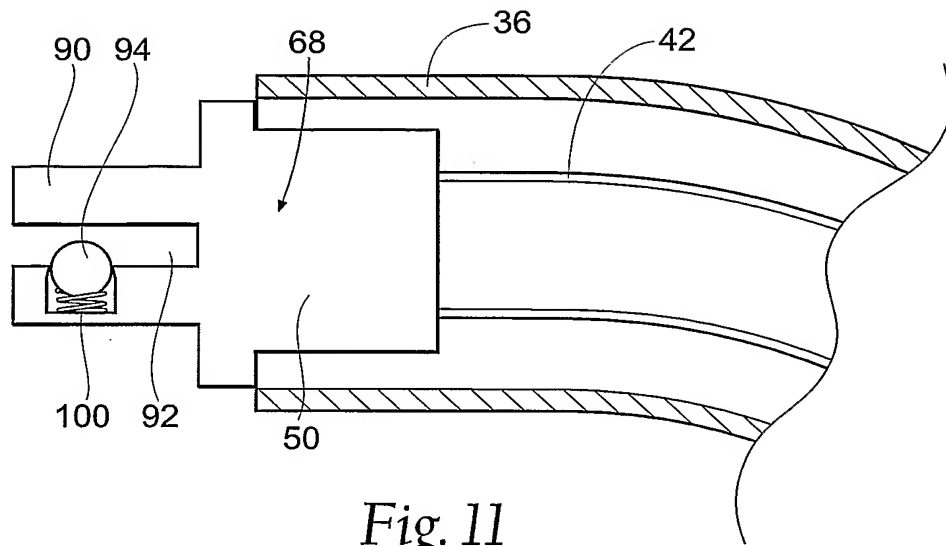


Fig. 10A(2)







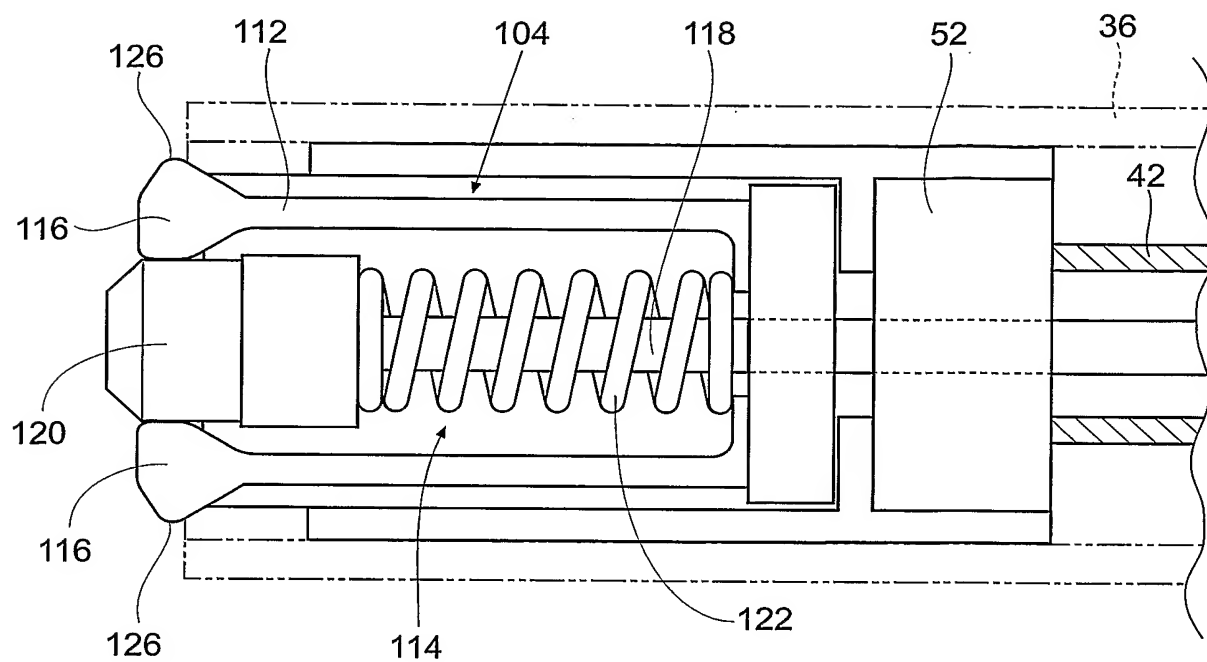


Fig. 13A

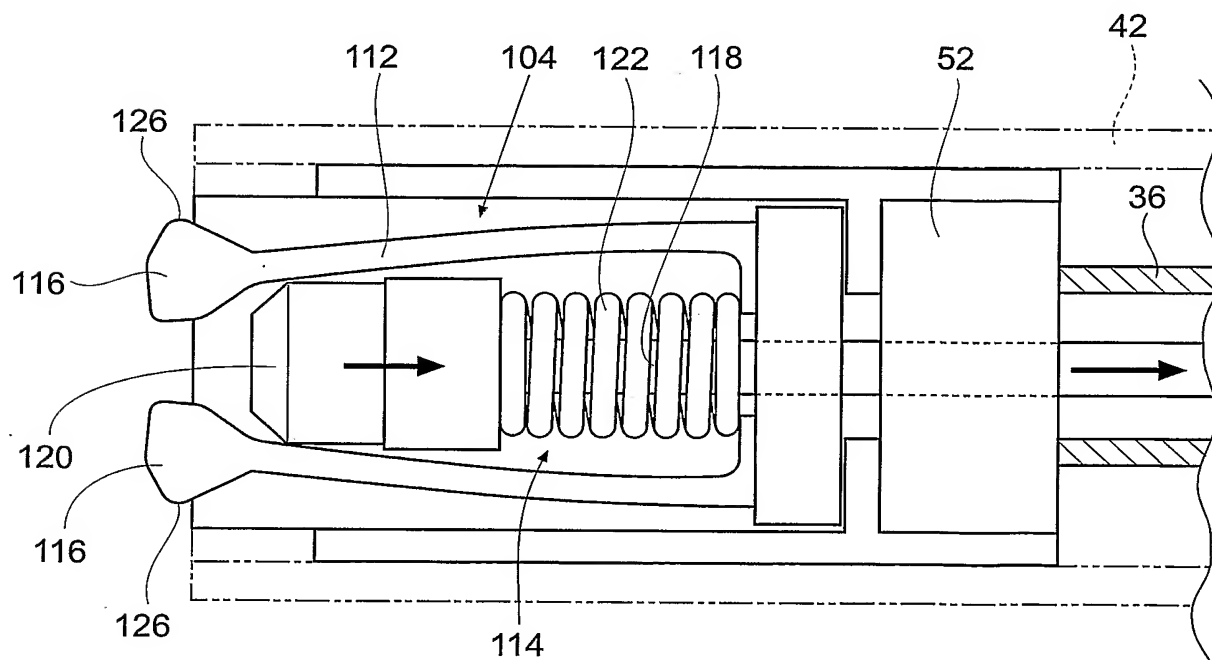


Fig. 13B

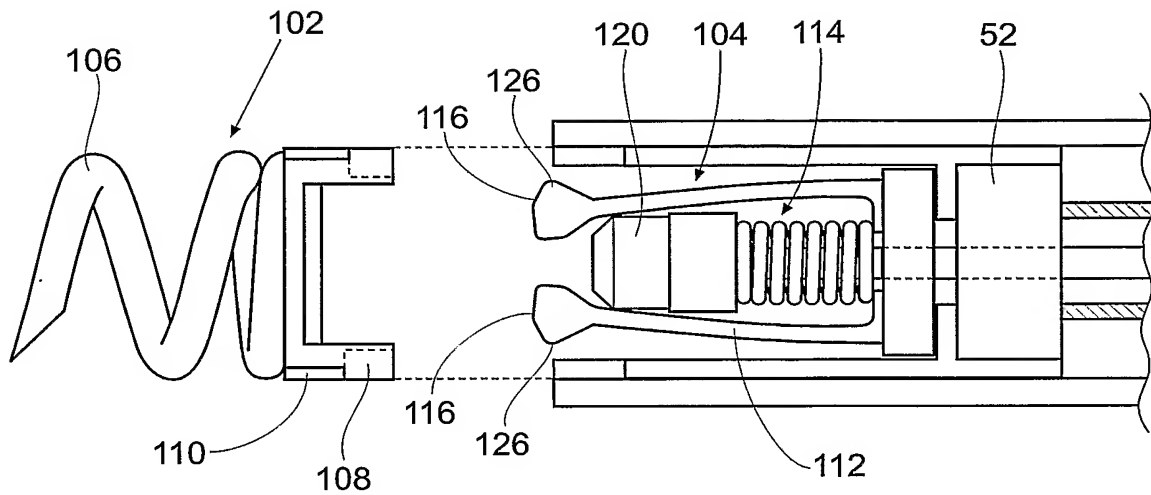


Fig. 14A

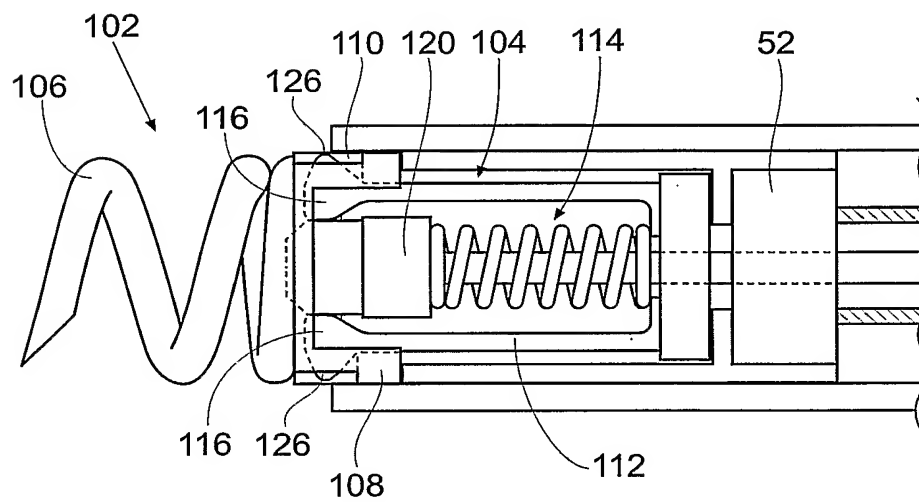
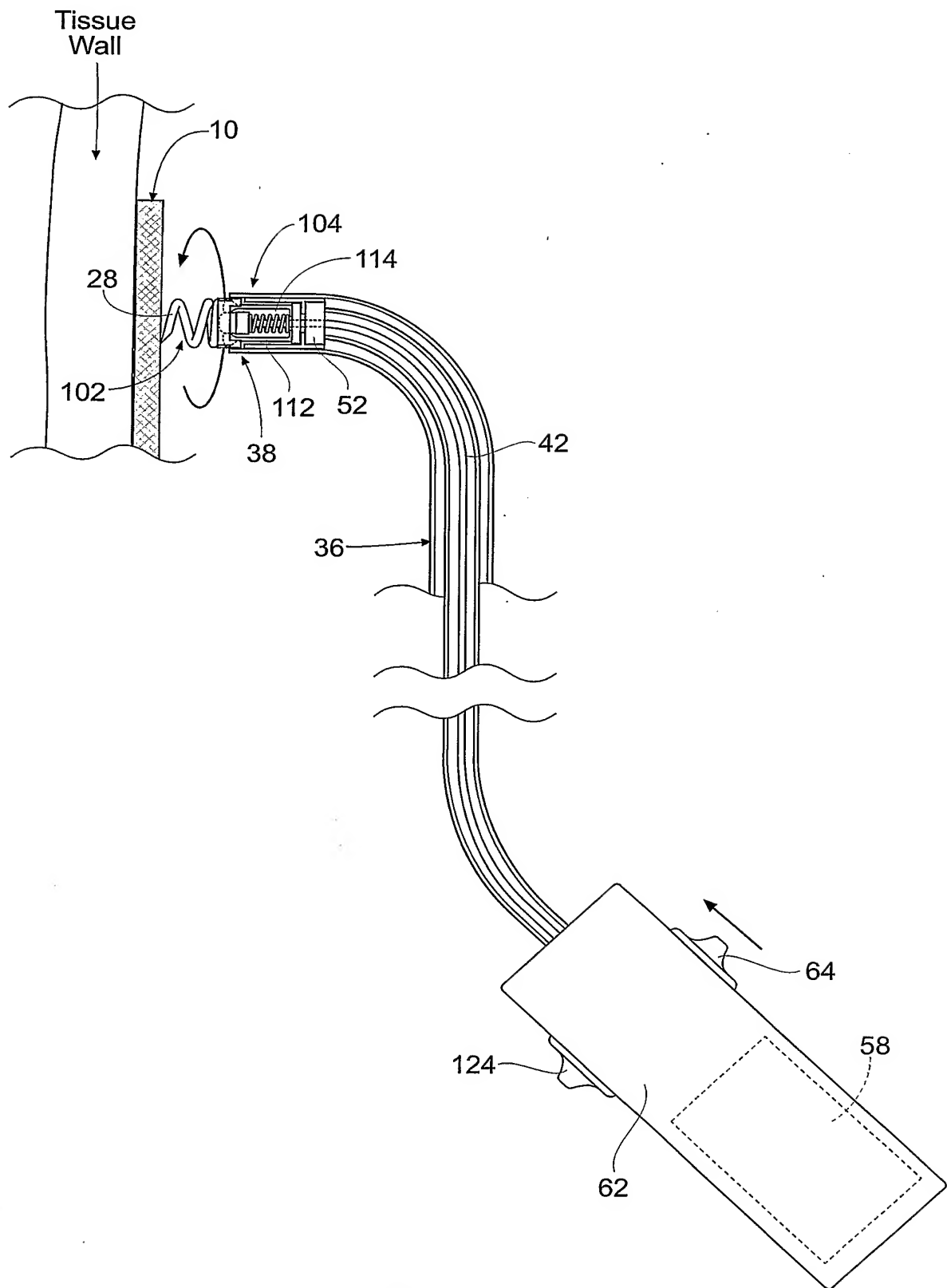


Fig. 14B

*Fig. 15A*

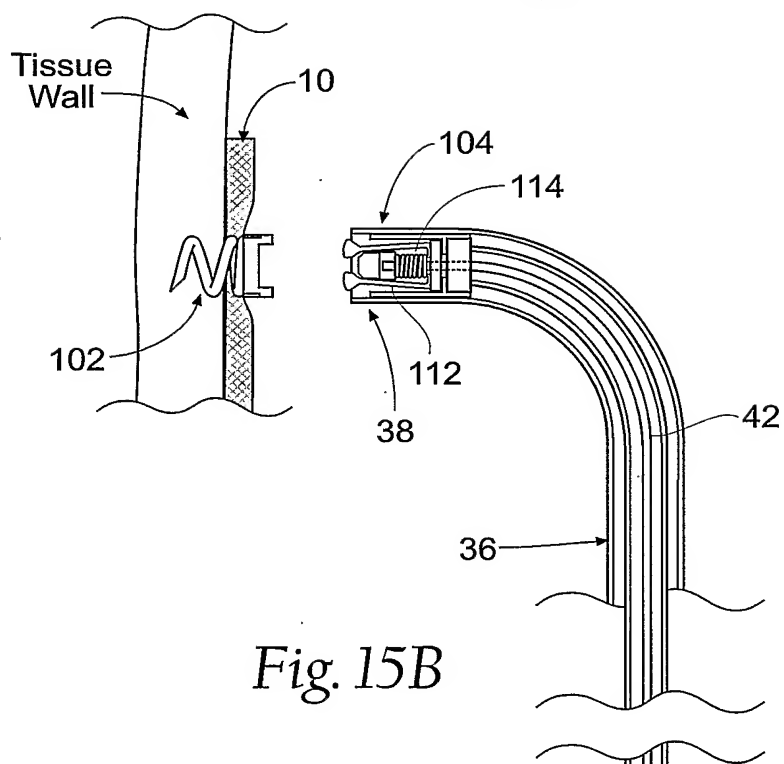


Fig. 15B

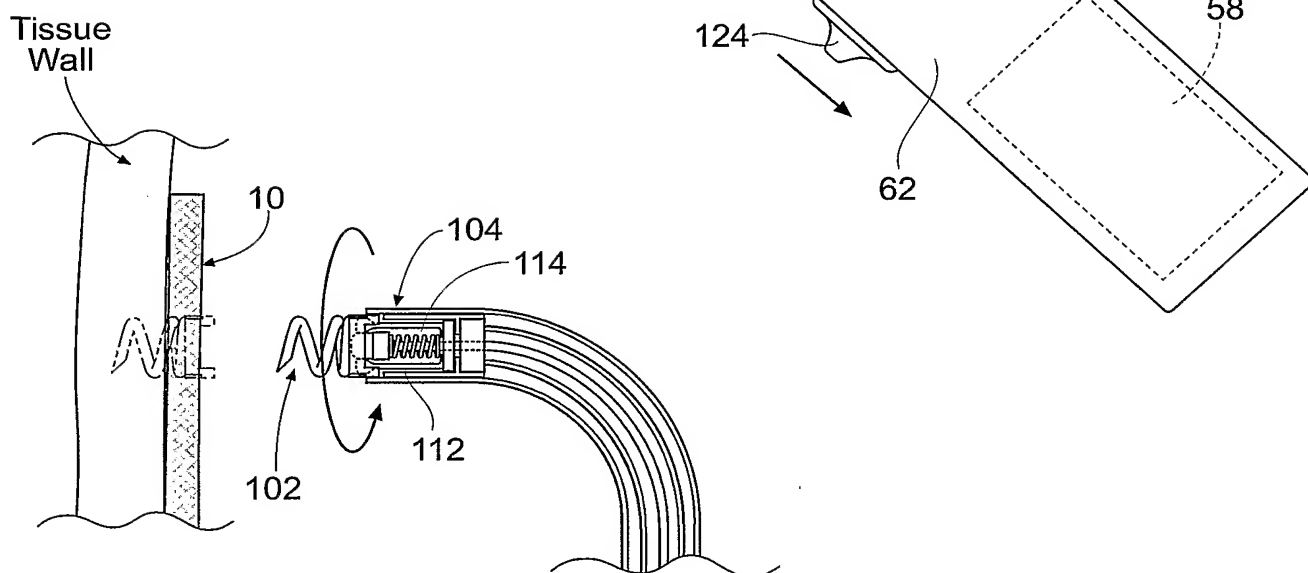


Fig. 15C

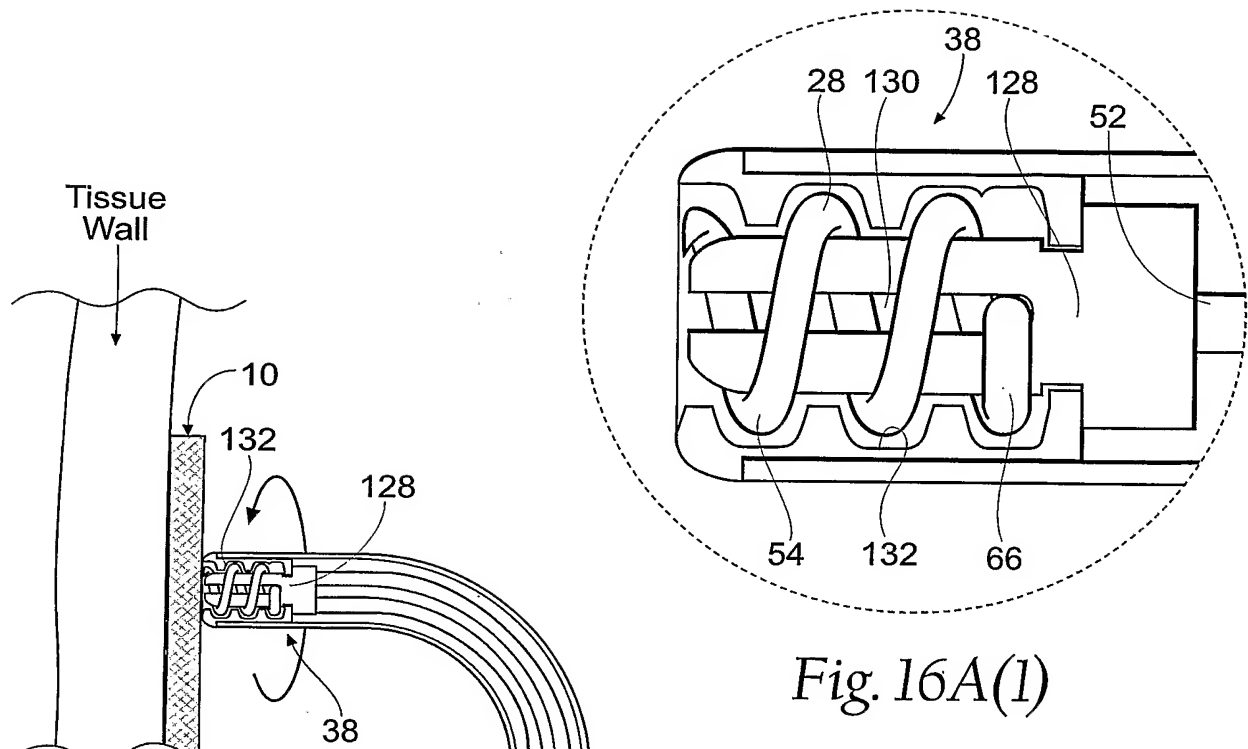
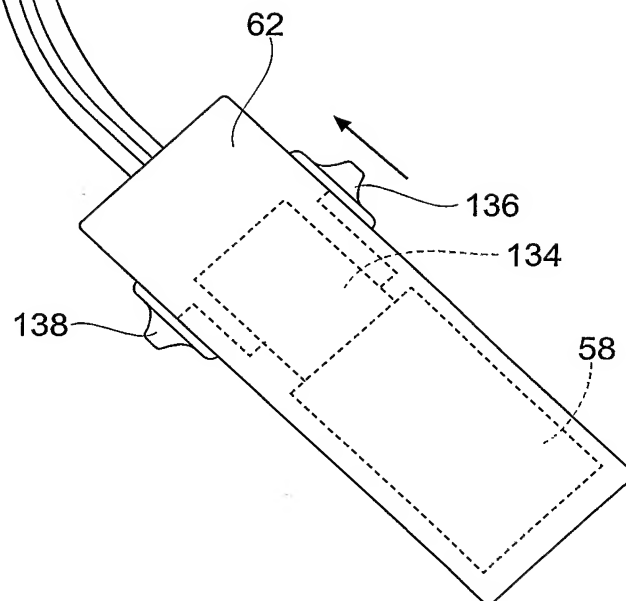
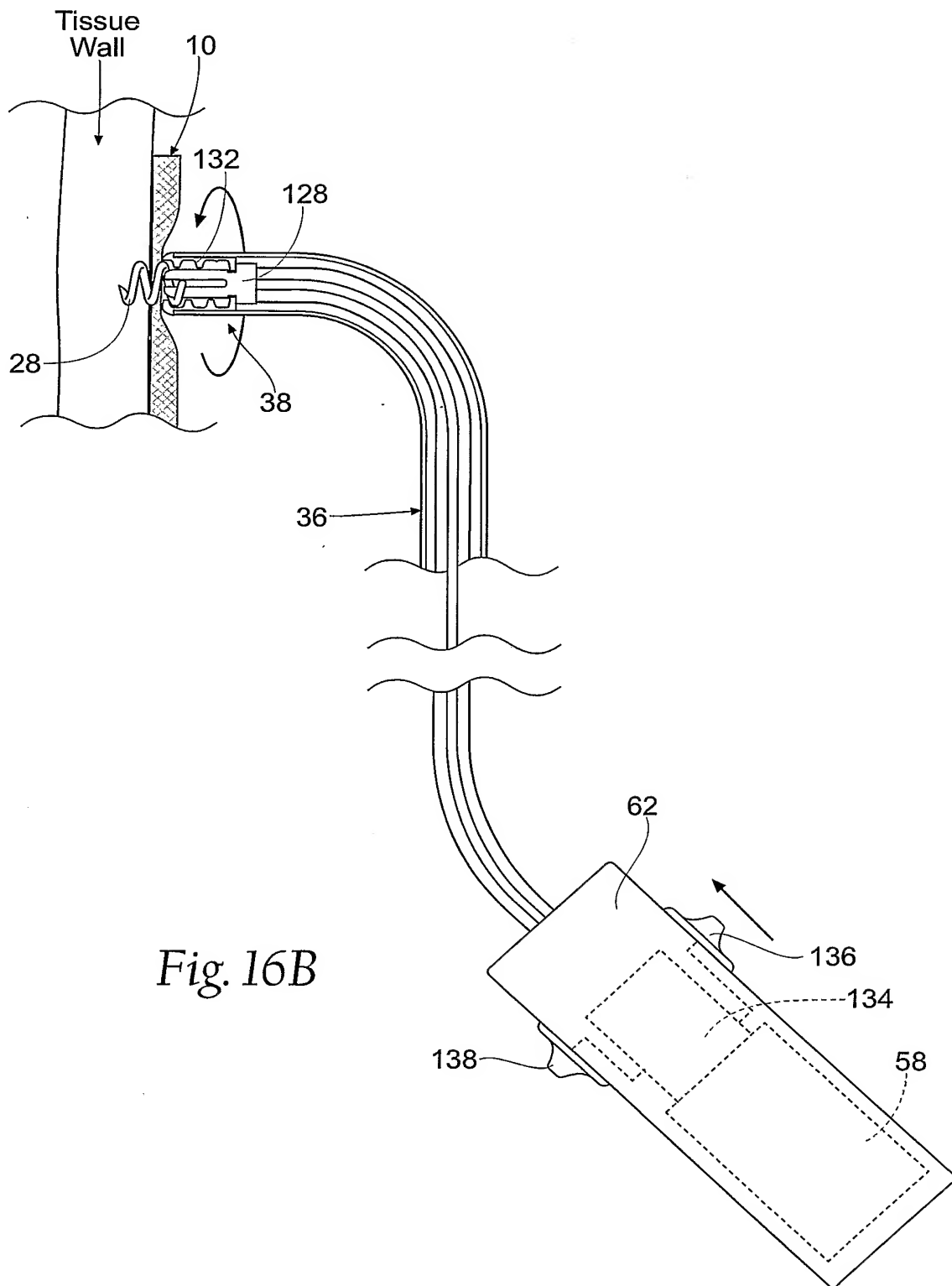
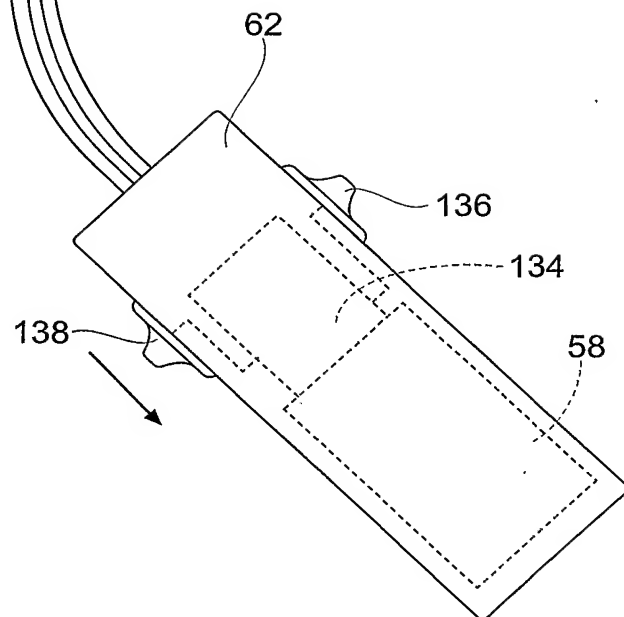
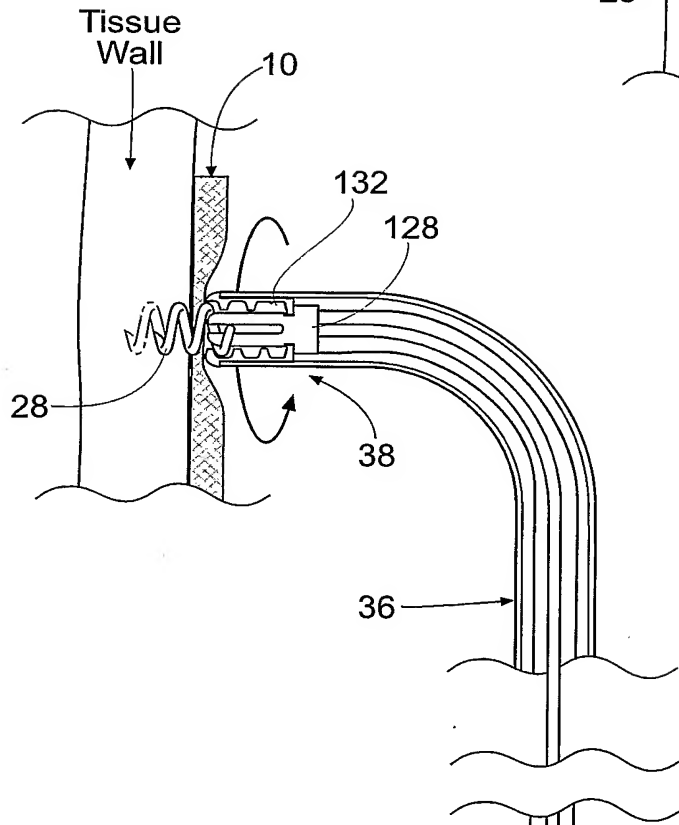
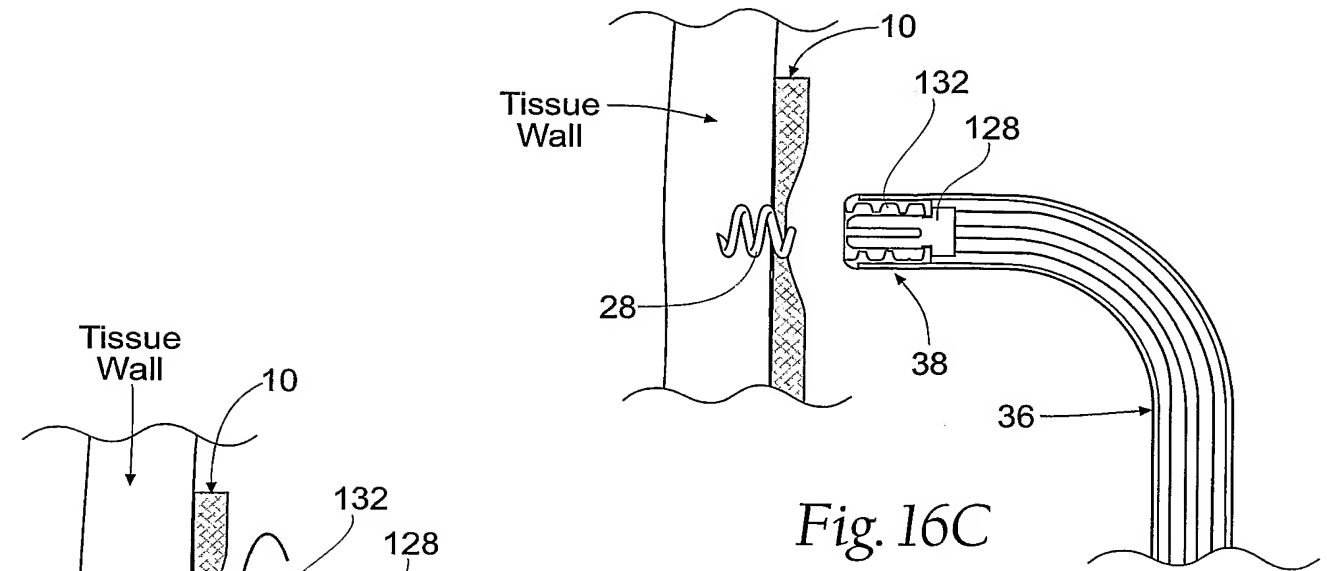
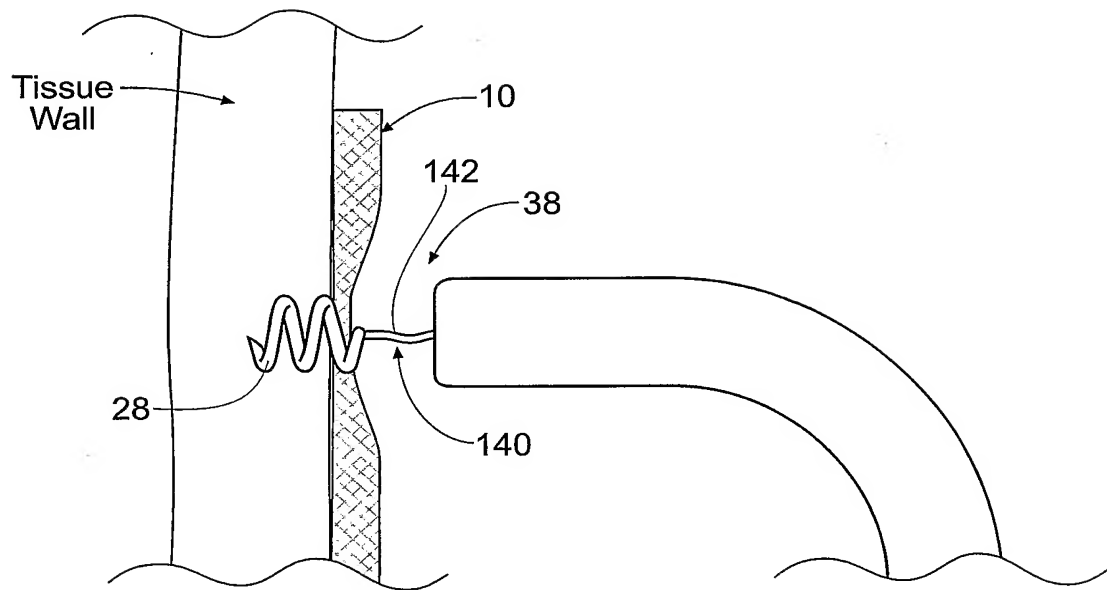
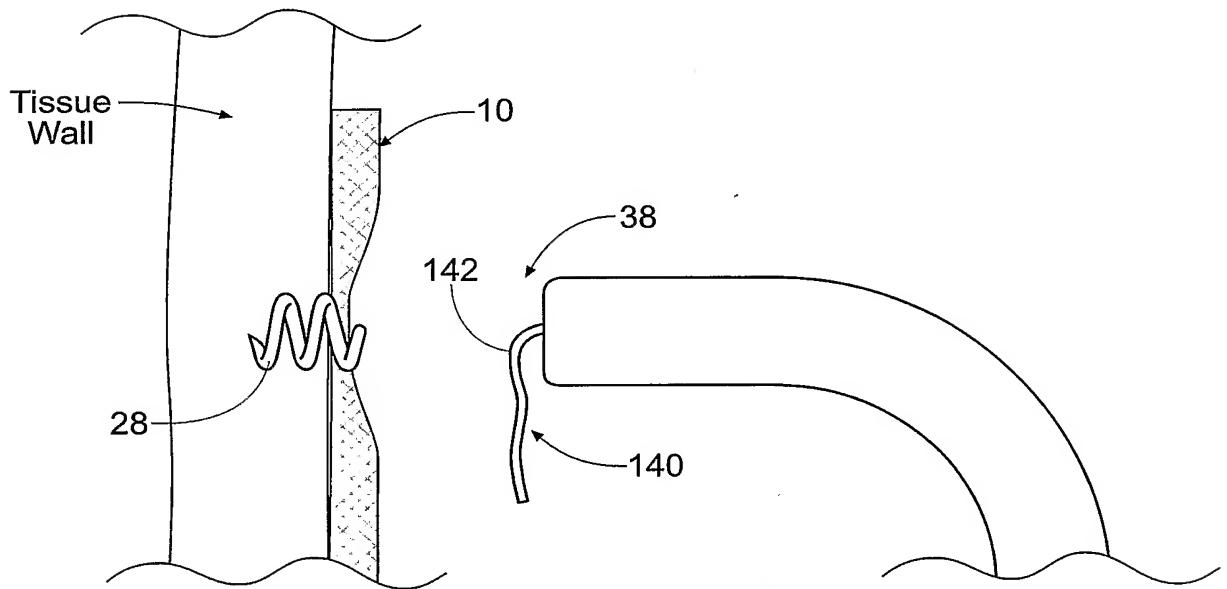


Fig. 16A(2)







*Fig. 17A**Fig. 17B*

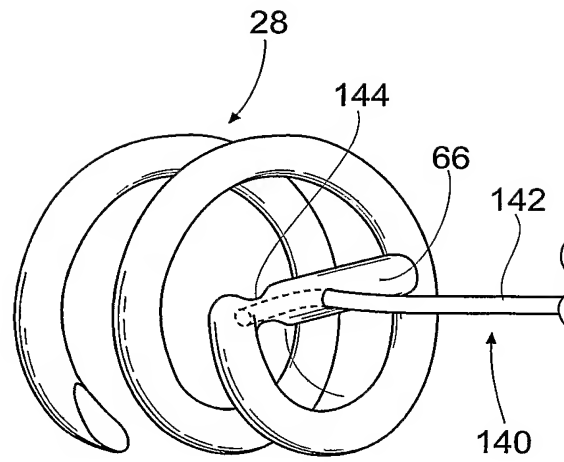


Fig. 18A

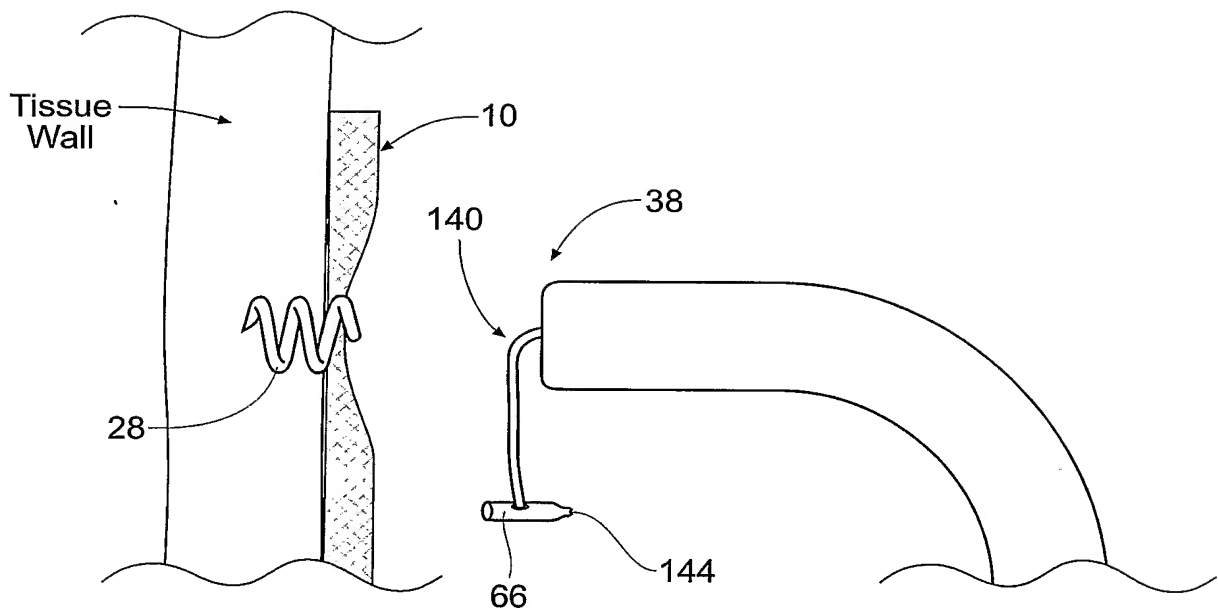


Fig. 18B

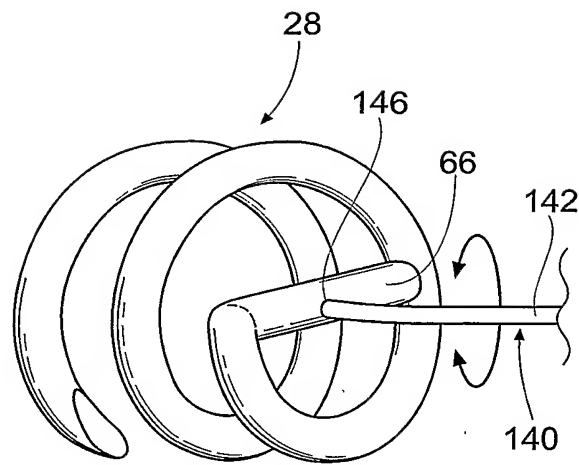


Fig. 19A

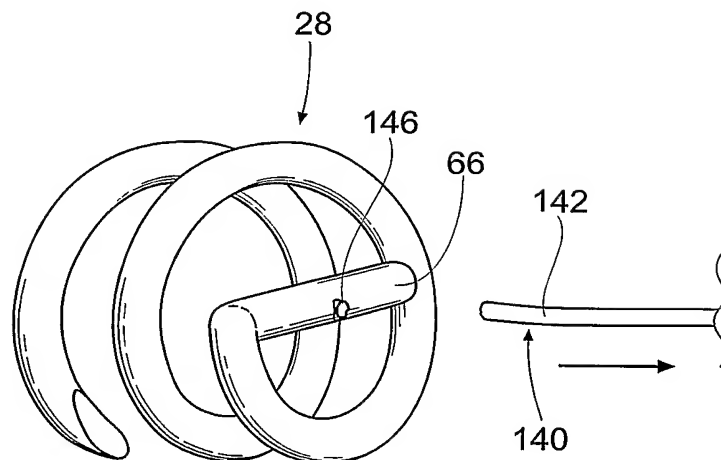


Fig. 19B

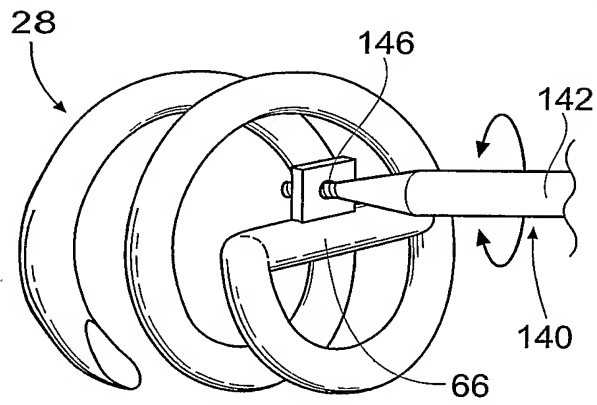


Fig. 20A

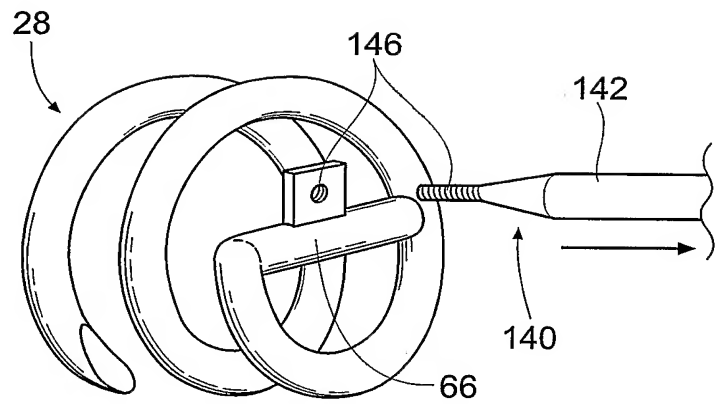


Fig. 20B

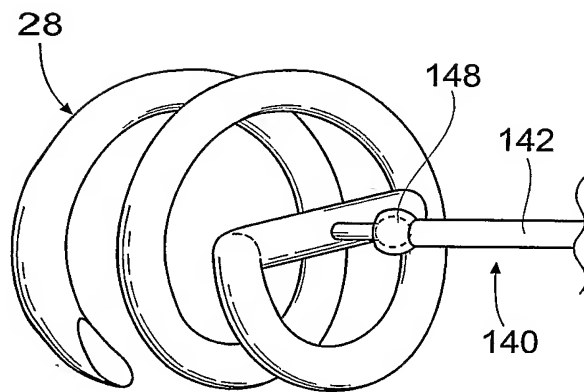


Fig. 21A

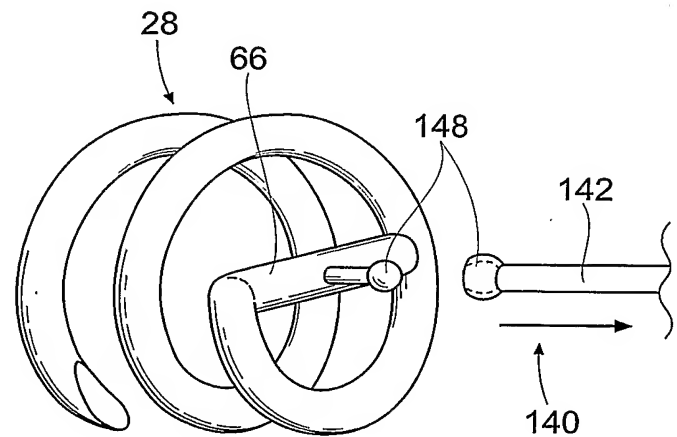


Fig. 21B

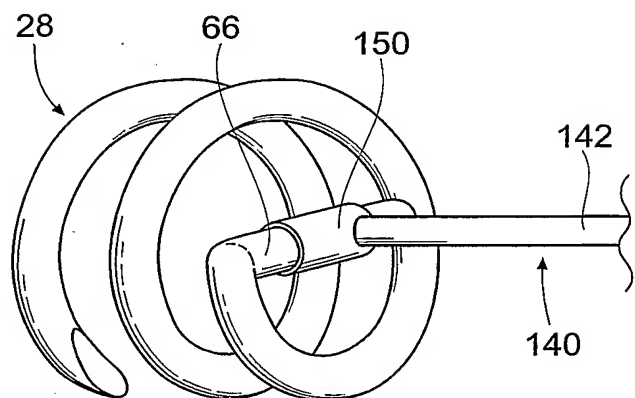


Fig. 22A

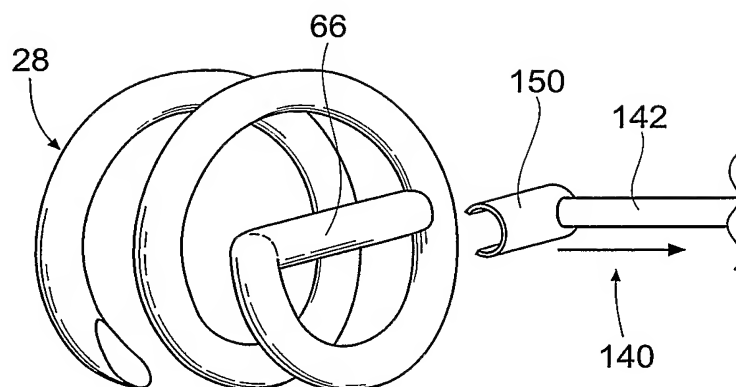


Fig. 22B

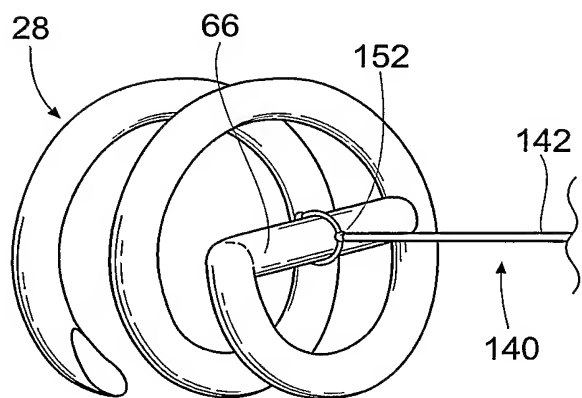


Fig. 23A

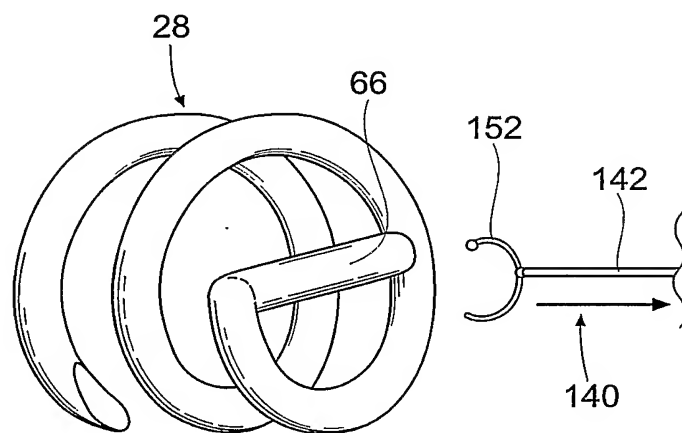


Fig. 23B

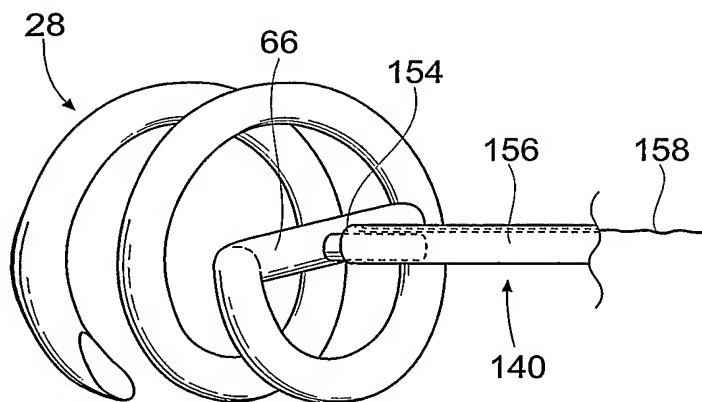


Fig. 24A

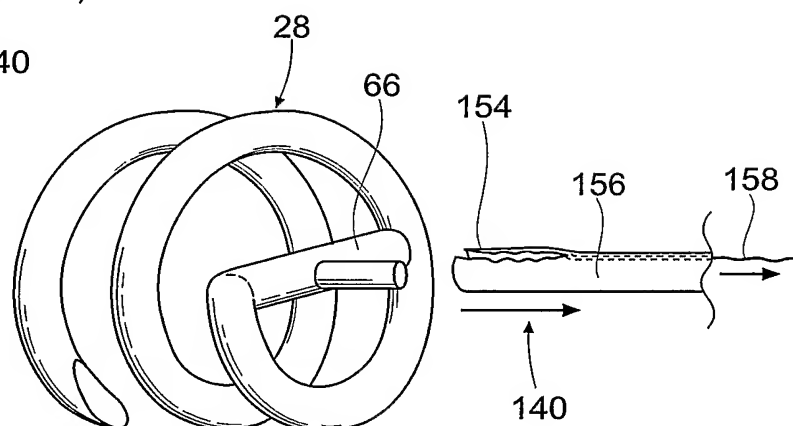


Fig. 24B

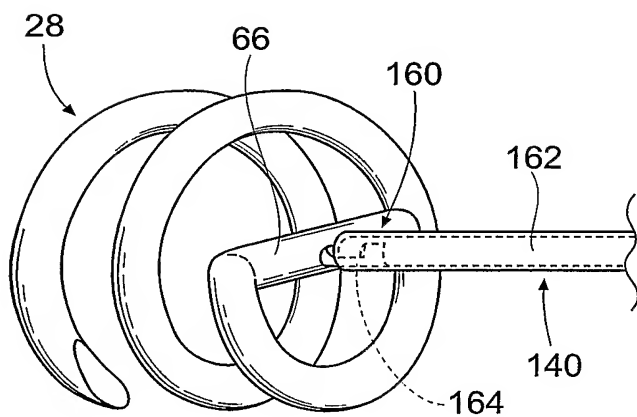


Fig. 25A

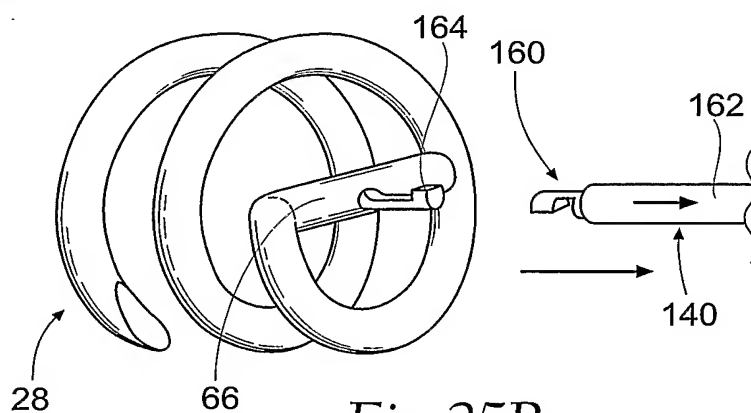


Fig. 25B

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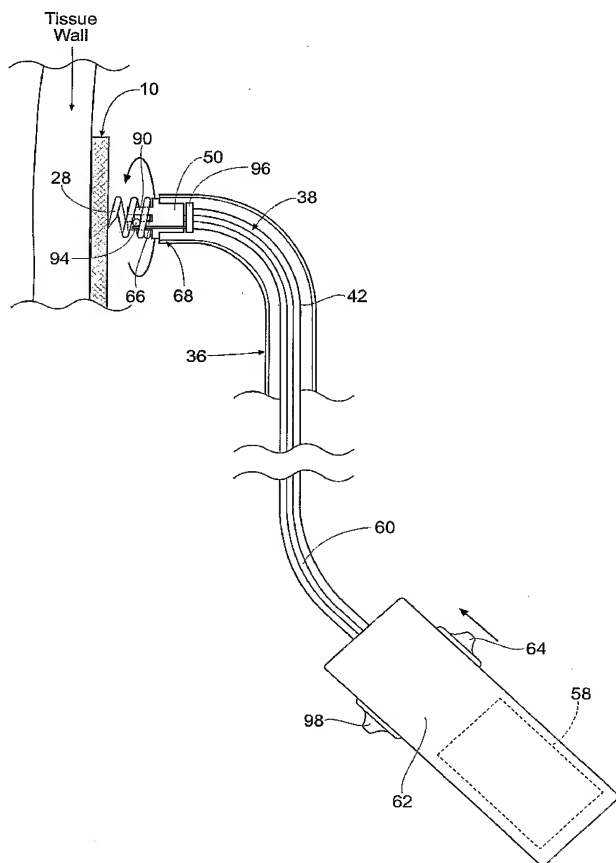
(74) Agents: **RYAN, Daniel, D.** et al.; P.O. Box 26618, Milwaukee, WI 53226 (US).

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[Continued on next page]

(54) Title: SYSTEM AND METHOD FOR ATTACHING AN INTERNAL PROSTHESIS



(57) Abstract: Systems and methods introduce and deploy prosthesis into a blood vessel or hollow body organ by intra-vascular access. The prosthesis (20) is secured in place by fasteners (28), which are implanted by an applicator (62) that is also deployed by intra-vascular access. The applicator is configured to permit controlled, selective release of the fastener in a step that is independent of the step of implantation.



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B. FIELDS SEARCHED

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U.S. : 606/138,139,140,142,143;623/1.23

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,334,196 A (SCOTT et al) 2 August 1994 (02.08.1994), abstract, col. 4, ll. 62,col. 6, ll. 37,38	1-7,17-47



Further documents are listed in the continuation of Box C.



See patent family annex.

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(54) Title: DEVICES, SYSTEM, AND METHODS FOR GUIDING AN OPERATIVE TOOL INTO AN INTERIOR BODY RE-
GION

(57) Abstract: A guide device establishes a guide passage through a guide tube, through which an operative tool can be deployed into an interior body region for use. A steering assembly, in use, deflects or bends the distal end region of the guide tube, so that the operative tool can be placed in a desired orientation with respect to tissue. The steering assembly is desirable configured for single handed operation by the clinician. The steering assembly is also desirably configured to provide a mechanical advantage sufficient to translate relatively small increments of clinician control into relatively larger increments of guide tube deflection. In one arrangement, the steering assembly includes a rack and pinion linkage system. In another arrangement, the steering assembly includes a pivoting lever system.



WO 2007/046953 A2

**DEVICES, SYSTEM, AND METHODS FOR GUIDING
AN OPERATIVE TOOL INTO AN INTERIOR BODY REGION**

Related Applications

This application is a continuation-in-part of co-
5 pending United States Patent Application Serial No.
11/166,411, filed June 24, 2005, entitled "Endovascular
Aneurysm Repair System," which is a divisional of United
States Patent Application Serial No. 10/271,334, filed
October 15, 2002 (now United States Patent No.
10 6,960,217), which claims the benefit of United States
Provisional Patent Application Serial No. 60/333,937,
filed November 28, 2001, and entitled "Endovascular
Aneurysm Repair System," which are each incorporated
herein by reference. This application is also a
15 continuation-in-part of co-pending United States Patent
Application Serial No. 10/307,226, filed November 29,
2002, and entitled "Intraluminal Prosthesis Attachment
Systems and Methods" and a continuation-in-part of co-
pending United States Patent Application Serial No.
20 10/669,881, filed September 24, 2003, and entitled
"Catheter-Based Fastener Implantation Apparatus and
Methods with Implantation Force Resolution," which are
each incorporated herein by reference.

Field of the Invention

25 This invention relates generally to devices,

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systems, and methods that guide operative tools within a vessel or hollow body organ.

Background of the Invention

In the field of steerable guide systems, there is a need to translate a comfortable rotational manipulation by a physician into an effective distal deflection. There is also a need for a guide system that would provide a mechanical advantage such that a minimal manipulation by a physician would provide a sufficient distal deflection.

Summary of the Invention

The invention provides improved devices, systems, and methods for guiding an operative tool for use within an interior tissue region.

According to one aspect of the invention, a guide device comprises a guide tube that establishes a guide passage through which an operative tool can be deployed into an interior body region for use. The device includes a steering assembly that, in use, deflects or bends the distal end region of the guide tube, so that the operative tool can be placed in a desired orientation with respect to tissue.

The steering assembly is desirable configured for single handed operation by the clinician. The steering assembly is also desirably configured to provide a mechanical advantage sufficient to translate relatively small increments of clinician control into relatively larger increments of guide tube deflection.

In one embodiment, the steering assembly includes a rack and pinion linkage system that translates rotation of an actuator into linear movement of a rack into rotation of a gear train, to apply a tension force to a deflecting component coupled to the distal end region of the guide tube.

In another embodiment, the steering assembly includes a pivoting lever system that translates rotation

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of an actuator into linear movement of a slider into pivotal movement of a lever arm, to apply a tension force to a deflecting component coupled to the distal end region of the guide tube.

5 In both embodiments, the tension applied to the deflecting component bends or deflects the distal end region of the guide tube.

10 In one embodiment, the operative tool applies one or more fasteners to tissue. The steerable guide device makes it possible to accurately orient and maintain the fastening tool with respect to tissue, without the need to place a steering mechanism on-board the fastening tool or without the need to equip the fastening tool with a guide wire lumen.

15 **Brief Description of the Drawings**

Fig. 1 is a plane view of a steerable guide device in its straightened, undeflected position.

Fig. 1A is a plan view of a dilator for use with the steerable guide device of Fig.1.

20 Fig. 2 is a plane view of the steerable guide device shown in Fig. 1 in association with an operative tool.

Fig. 3 is a plane view of the steerable guide system shown in Fig. 1, showing a clinician's hand rotating an actuator knob to operate an associated steering assembly to cause bending or deflection of the distal end region of the device.

Fig. 4 is a plane view of the steerable guide device shown in Fig. 3 in association with an operative tool.

30 Figs. 5A, 5B, and 5C are plane views of the distal end region of the device shown in Fig. 4, showing the presence of a radiopaque marker that is shaped to provide a different visual image depending upon its orientation, respectively, anteriorly (Fig. 5A), posteriorly (Fig. 5B), or laterally (Fig. 5C).

35 Fig. 6A is an interior section view of the distal

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end region of the device shown in Fig. 3, taken generally along line 6A-6A of Fig. 6B.

Fig. 6B is a perspective end view, partially broken away, of the distal end region of the device shown in section in Fig. 6A.

Fig. 6C is a perspective end view, partially broken away, of an alternative embodiment of the distal end region of the device shown in Fig. 6B.

Fig. 6D is a perspective end view, partially broken away, of the distal end region of an alternative embodiment of the device shown in Fig. 6A, and showing multiple control lumens to direct the distal end region in more than one direction.

Fig. 6E is a plane view of the distal end region of the alternative embodiment shown in Fig. 6D, and showing the distal end region having two 90 degree deflections.

Fig. 7 is a plane view, partially diagrammatic, showing the attachment of the guide tube of the device to the handle of the device, and the formation of an interior passage through the handle and guide tube to receive an operative tool.

Fig. 8 is a plane side view, of the device shown in Fig. 1, with the handle broken away and in section to show the components of the steering assembly within the handle; the operation of which bends or deflects the distal end region in the manner shown in Fig. 3.

Fig. 9 is an exploded view, with parts partially broken away and in section, showing the main components of the device, including the components of the steering assembly shown in Fig. 8.

Fig. 10 is a section view taken generally along line 10-10 in Fig. 8.

Fig. 11 is a plane side view, of the device shown in Fig. 3, with the handle broken away and in section to show the operation of the steering assembly within the

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handle to bends or deflects the distal end region of the device.

Fig. 12 is side plane view of a steerable guide device, with the handle broken away and in section, showing an alternative steering assembly in its neutral position, in which the distal end region of the guide tube is straight and undeflected.

Fig. 13 is side plane view of a steerable guide device shown in Fig. 12, with the handle broken away and in section, showing the operation of the alternative steering assembly to bend or deflect the distal end region of the guide tube.

Fig. 14 is a side view of the steerable guide device and associated operative tool, as also generally shown in Fig. 4, with the operative tool shown to be an endovascular fastener oriented by the guide device for the application of a fastener to a prosthesis deployed in a tissue region.

Description of Preferred Embodiments

Although the disclosure hereof is detailed and exact to enable those skilled in the art to practice the invention, the physical embodiments herein disclosed merely exemplify the invention which may be embodied in other specific structures. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

I. OVERVIEW

Fig. 1 shows a steerable guide device 10. The steerable guide device 10 comprises a flexible guide tube 12 carried by a handle 14. The flexible guide tube 12 may be constructed, for example, by extrusion using standard flexible, medical grade plastic materials. Further details of the guide tube 12 will be described later.

The handle 14 may be constructed, for example, from

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molded plastic. The handle 14 is sized to be conveniently held by a clinician, to introduce the guide tube 12 into an interior body region that has been targeted for treatment.

5 As used in this disclosure, the term "proximal" refers to the aspect of the device that is, in use, held by the clinician, while the term "distal" refers to the aspect of the device that is, in use, positioned in or toward the body.

10 The purpose of the guide device 10 is to establish an open path through which an operative tool 16 can be deployed for use. For this purpose (see Fig. 2), the guide device 10 includes an interior guide passage 18. The guide passage 18 extends through an interior portion
15 of the handle 14 continuously into and through the guide tube 12. Entrance into the guide passage 18 is provided by a proximal opening 20 formed in the handle 14. The guide passage 18 terminates at an opening 22 at the distal end of the guide tube 12. Further details of the
20 configuration of the guide passage 18 will be described later.

As Fig. 2 shows, the guide passage 18 is sized and configured so that, in use, the operative tool 16 can be inserted through the proximal opening 20 and advanced
25 through the passage 18 outwardly beyond the distal opening 22. Use of the guide device 10 in this manner facilitates the deployment and positioning of the operative tool 16 that, by construction, may be less flexible and harder to manipulate than the guide tube 12
30 itself.

The guide tube 12, while flexible, preferable has a plastic memory or bias that normally orients the distal end region of the guide tube 12 in an essentially straight configuration, as shown in Fig. 1. To enable
35 greater control of the orientation of the distal end

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region of the guide tube 10, the guide device 10 includes a steering assembly 24. In operation, the steering assembly 24 deflects the distal end region of guide tube 12 out of its essentially straight configuration and into a bent or deflected configuration, as shown in Fig. 3.

In its essentially straight configuration, the guide tube 12 is well oriented for deployment into an interior body region, e.g., through an intra-vascular or cannulated access path. During such deployment, the guide tube 12 may be passed over a conventional guide wire, which can be inserted through the interior passage 18. Or alternatively, the guide tube 12 may be used with a dilator 60 (see Fig. 1A) which may be inserted through the interior guide passage 18. The dilator 60 features a tapered nosecone 62 on its distal end, a Luer type connector 64 on its proximal end, and a shaft 66 coupling the nosecone 62 to the Luer connector 64. The dilator 60 desirably includes a guide wire lumen 68 extending throughout the length of the dilator. In use, the tapered nosecone 62 extends past the distal tip or opening 22 of the steerable guide catheter 10 to facilitate access to the intra-vascular or cannulated access path and provide improved tracking onto the guide wire.

Upon deployment of the guide tube 12 to a desired body region (and withdrawal of the guide wire and dilator 60, if used), a clinician can operate the steering assembly 24 to deflect the distal end region of the guide tube 12 in its bent or deflected condition. A radiopaque marker M (see Fig. 3) can be placed on the distal end region to permit fluoroscopic visualization of the orientation of the deflected end region. In its bent or deflected configuration, the distal passage end 22 can be oriented in a desired relationship with a targeted tissue surface in the body region.

Desirably -- as Figs. 5A, 5B, and 5C show -- the

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radiopaque marker M forms a partial ring (i.e., C-shaped) or comparable shape that changes depending upon orientation, so that the radiopaque image is visually distinct when observed in different orientations, e.g.,
5 presenting an upward U-shape when in an anterior orientation (Fig. 5A); or a downward U or "little-N" shape when in a posterior orientation (Fig. 5B); or an edge-on shape when in a lateral orientation (Fig. 5C). It should be appreciated that multiple radiopaque markers
10 can also be used to provide an image which is visually distinct when observed in different orientations.

Desirably (as Fig. 3 shows), the guide tube 12 is placed into its bent or deflected configuration before passage of the operative tool 16 through the passage 18.
15 Once in its bent or deflected configuration, as Fig. 4 shows, the operative tool 16 can be advanced through the passage 18 and guided by the bent configuration into the desired relationship with the tissue surface for use.

The steering assembly 24 holds the distal end of the
20 guide tube 12 in its deflected condition, thereby maintaining the operative tool 16 in its desired relationship during use. The steerable guide tube 12 obviates the need to equip the operative tool 16 with an on-board steering mechanism or a guide wire lumen.

25 As Figs. 3 and 4 show, the steering assembly 24 is desirable configured for single handed operation by the clinician. The steering assembly 24 is also desirably configured to provide a mechanical advantage sufficient to translate relatively small increments of clinician
30 control into relatively larger increments of guide tube deflection.

As will be described in greater detail later, and as Fig. 3 generally shows, the steering assembly 24 includes an actuator 26 that can be manipulated by the clinician.
35 The actuator 26 is coupled through a linkage system 28 to

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a deflecting component 30, which is coupled to the distal end region of the guide tube 12.

In general operation, manual force applied by the clinician to the actuator 26 is translated by the linkage system 28 into a pulling force or tension exerted on the deflecting component 30, which deflects or bends the distal end region of the guide tube 12. The linkage system 30 is desirably configured with a mechanical advantage that amplifies relatively small increments of movement of the actuator 26 into relatively larger increments of movement of the deflecting component 30.

Further details of particular embodiments of the guide tube 12 and the steering assembly 24 will now be described.

A. Components of the Guide Tube

Referring to Figs. 6A and 6B, in the illustrated embodiment, the guide tube 12 comprises a main lumen 32, which constitutes a portion of the interior passage 18, already described. The guide tube 12 also includes a control lumen 34. The deflection component 30, previously described, extends through the control lumen 34.

The illustrated embodiment shows one control lumen 34 and one deflection component 30. It should be appreciated that multiple control lumens (and deflection components) can be provided, if desired. As can be seen in Figs. 6D and 6E, multiple control lumens would provide the ability to direct the flexible guide tube 12, (e.g., the distal end region) of the steerable guide 10 in more than one direction. For example, two control lumens 34, 34' oriented 180 degrees apart (along with two deflection components 30, 30') would allow the distal end region to be deflected 90 degrees in two directions within one plane. This feature would allow for additional steering control to accurately position the distal opening 22 at the targeted tissue site.

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In the illustrated embodiment, the control lumen 34 is also shown to extend outside the main lumen 32. It should be appreciated that the control lumen 34 can extend inside the main lumen 32, or the main lumen 32 and the control lumen 34 can be formed as a composite.

Both the main lumen 32 and the control lumen 34 desirably include a liner 36. Each liner 36 preferably comprises a material with a low coefficient of friction, such as PTFE, although other materials having comparable mechanical properties can be used. The presence of the liner 36 in the main lumen 32 reduces friction to ease the passage of the operative device 18 through the main lumen 32. The presence of the liner 36 in the control lumen 34 reduces friction and this moderates the pulling force or tension necessary to manipulate the deflecting component 30.

The guide tube 12 also desirably includes a reinforcement sheath 38. The reinforcement sheath 38 envelopes both the main lumen 32 and control lumen 34. The reinforcement sheath 38 can have multiple shape configurations, can be made of multiple materials, and can be arranged in multiple patterns. Patterns can range from a simple coil to a complex braid arrangement. The pattern can be uniform or can vary along the length of the catheter tube 12. In the illustrated embodiment, the reinforcement sheath 38 is in the form of a braid made of round wire made, e.g., from stainless steel, titanium, cobalt alloys, polymers, and natural fibers.

The guide tube 12 also desirably includes a tip reinforcing element(s) 40. The reinforcing element 40 is disposed at or near the distal opening 22 of the passage 18, and serves to resist collapse or distortion of the main lumen 32 during deflection as a result of pulling on the deflecting component 30.

In a desired embodiment, (see Fig. 6B), the tip

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reinforcing element 40 comprises a metallic ring, such as a uniform ring, but other shapes and materials are also contemplated. As seen in Figs. 6A and 6B, the tip reinforcing element 40 is shown disposed over the reinforcement sheath 38. Alternatively, the tip reinforcing element 40 and the reinforcement sheath 38 can comprise a composite structure.

In the desired embodiment, the deflecting component 30 makes a continuous loop completely around the tip reinforcing element 40 and returns back through the control lumen 34 into the handle 14, where it is coupled to the linkage system 28, as will be described in greater detail later. In an alternative embodiment (see Fig. 6C), the deflecting component 30 loops around only a portion of a reinforcing element 41. As shown, the reinforcing element 41 comprises more than one ring (i.e., two or more individual rings) coupled together with at least one coupling element 43. In this configuration, the deflecting component 30 may be looped around one or more coupling element(s) 43.

The guide tube 12 also desirably includes a cover 42. The cover 42 envelopes all of the internal structures heretofore described, forming a composite structure. The cover 42 can be made of different types of material or of a uniform material with different physical characteristics throughout the length of the guide tube 12. The cover 42 can be of uniform thickness, or the thickness can vary along the length of the guide tube 12. In a preferred embodiment, the cover is made of a polymer material of differing hardness. The softest portion is located at the distal portion of the guide tube 12 (near the opening 22) and the stiffer portion is located at the proximal portion of the guide tube 12 (within the handle 14). The cover 42 can also include a material within the polymer which allows the cover 42 to be radiopaque or a

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material that reduces friction.

The tip reinforcing element 40, 41 and/or reinforcement sheath 38 can also be used as radiopaque markers. Alternatively, or in combination, one or more radiopaque markers M can be attached to the distal end of the catheter assembly 12. The use of radiopaque materials makes it possible to gauge the deflected orientation of the guide tube 12. A given radiopaque marker can be made from platinum. Still, other materials (and different shapes) can be used.

As Fig. 7 shows, the guide tube 12 extends into the distal end of the handle 14. A transition shaft 44 is connected at one end to the proximal end of the guide tube 12 (where the cover 42 is stiffer) and at the other end to a sealing element 46 that occupies the proximal-most region of the handle 14. The sealing element 46 includes an interior lumen 48 that comprises an extension of the interior passage 18, and also includes the proximal opening 20. The transition shaft 44 also includes an interior lumen 50 that also forms an extension of the interior passage 18, linking the main lumen 32 of the guide tube 12 in communication with the proximal opening 20. The transition shaft 44 can be an integrated component of the guide tube 12.

The sealing element 46 desirably includes an in-line hemostatic valve assembly 52 at or near the proximal opening 20 of the passage 18. The valve assembly 52 prevents blood or fluid loss by sealing the proximal opening 20 when an operative tool 16 is within the passage 18, as well as when no operative tool 16 is present in the passage 18.

The valve assembly 52 desirably includes a main seal component 54 and a lip seal component 56, which can comprise separate or integrated components. The main seal component 54 seals the proximal opening 20 in the absence

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of an operative tool 16 in the passage 18. The lip seal component 56 seals upon insertion of the operative tool 16 through the proximal opening 20 into the passage 18.

5 An infusion valve 58 can also be coupled to the passage 18 through the sealing element 46. In this way, fluid can be conveyed through the passage 18 into the interior body region, e.g., to flush materials from the passage 18 during use.

10 As described, the guide tube 12 is secured to the handle 14 and does not rotate relative to the handle 14. To rotate the guide tube 12, the clinician must rotate the handle 14.

B. Components of the Steering Assembly

1. The Actuator

15 It should be appreciated that the actuator 26 of the steering assembly 24 can take many forms, such as a sliding lever or a pistol grip. The actuator 26 can be located at many locations on the handle 14, such as the proximal end, the distal end, or the mid-portion. In the
20 embodiment shown in Figs. 1 to 4, the actuator 26 takes the form of a fluted knob that is rotationally attached to the distal end of the handle 14. The knob 26 is positioned so that it can be rotated by the thumb of the clinician's hand that holds the handle 14. As shown in
25 Fig. 3, the handle 14 may be held in the palm of the hand while the knob 26 is manipulated by the thumb.

In the illustrated arrangement (best shown in Figs. 8 and 9), the knob 26 includes front and rear thrust bearing surfaces 132 and 134. These thrust bearing
30 surfaces can be integral to the knob component or they can be separate components which are added to the knob 26 to make a complete assembly. Front and rear journals 136 and 138 on the handle 14 support the thrust bearing surfaces 132 and 134, so that the knob 26 can be easily
35 rotated relative to the distal end of the handle 14 by

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movement of the thumb.

2. The Linkage System

a. Rack and Pinion Gear Assembly

In the illustrated arrangement, the linkage system
5 28 translates rotational movement of the actuator knob 26
into a linear force direction. To affect this translation
(see Figs. 8 and 9), the linkage system 28 includes a
female threaded shaft 140 formed within the knob 26,
which rotates in common with the knob 26, and a threaded
10 male component 146 that is coupled to a slider 142, which
is mounted for linear movement in a channel 144 within
the handle 14. It should be appreciated that the thread
placement on both of these elements could be reversed.
The threads can take any form and/or type, and can be
15 self-locking or non-locking. In a preferred arrangement,
the threads on the female threaded shaft 140 and the male
threaded component 146 are locking.

The slider 142 is restrained by the channel 144 from
twisting or rotating. Coupled to the slider 142, which is
20 kept from twisting or rotating within the channel 144,
the threaded component 146 is likewise kept from
rotation.

The threaded male component 146 extends from the
slider 142 in the direction of the knob 26. The male
25 threads on the component 146 are configured to thread
into the female threads of the shaft 140 in response to
rotation of knob 26. Rotation of the knob 26
progressively moves the threaded component 146 within the
shaft 140. The slider 146 follows, moving in a linear
30 direction within the channel 144 fore (toward the distal
end of the handle 14) or aft (toward the proximal end of
the handle 14), depending upon the direction the knob 26
is rotated. Aft linear movement of the slider 142 within
the channel 144 is halted by a proximal stop 148. This
35 position (i.e., when the slider 142 rests in abutment

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against the stop 148) (as shown in Fig. 8) will be called in shorthand a "neutral position," because, in this position, the linkage system 28 is configured to apply no force upon the deflecting component 30.

5 When in the neutral position (as shown in Fig. 8), the male component 146 extends from the slider 142 a distance sufficient to thread a portion of the male component 146 within a portion of female threads of the shaft 140. When in the neutral position, rotation of the
10 knob 26 in a single predetermined direction (in the illustrated embodiment, clockwise from the clinician's view point) (see Fig. 11) advances the component 146 along the shaft 140 and draws the slider 142 in a linear forward direction within the channel 144 (i.e., toward
15 the knob 26). It should be appreciated that the direction for activation could be reversed (i.e., rotating the knob 26 advances the slider 142 in a linear direction away from the knob 26).

 The linkage system 28 is configured to translate
20 this linear forward movement of the slider 142 into a tension or pulling force on the deflecting component 30. To affect this translation, the linkage system 28 includes a rack and pinion gear system. More particularly (see Figs. 8 and 9), a rack 150 is coupled to slider 142
25 for linear movement in common with the slider 142. In the illustrated embodiment, the rack 150 extends in a direction away from the knob 26, into the more proximal region of the handle 14. There (as also shown in Fig. 10), the rack 150 engages a pinion gear 152. The pinion
30 gear 152 is coupled to a main gear 154, which is supported for rotation on a shaft within the handle 14. The main gear 154 is, in turn, coupled through another pinion gear 158 to a pick up reel 56, which is likewise supported for rotation on a shaft within the handle 14.
35 The proximal end of the deflecting component 30 is

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coupled to the pick up reel 156. The attachment can be accomplished, e.g., by crimping, tying, or adhesion.

Rotation of the pick up reel 156 in a predetermined direction (which, in the illustrated embodiment, is counterclockwise) applies a linear aft pulling force or
5 tension upon the deflecting component 30, thereby bending the distal end region of the catheter tube 12.

In an alternative arrangement (not shown), a spiral cut gear coupled to the knob could engage the rack to
10 move the rack in a linear direction in response to rotation of the knob.

As Fig. 11 best shows, the linkage system 28, as described, translates rotation of the knob 26, which draws the slider 142 toward the knob 26, into linear
15 forward translation of the rack 150. Linear forward translation of the rack 150 is, in turn, translated into rotation of the pinion gear 152 (which, in the illustrated embodiment, is clockwise). Rotation of the pinion gear 152 translates into an opposite rotation
20 (i.e., counterclockwise) of the main gear 154. Rotation of the main gear 154 translates into an opposite rotation (i.e., clockwise) of the pinion gear 158. Rotation of the pinion gear 158 translates into an opposite rotation (i.e., counterclockwise) of the pick up reel 156.
25 Rotation of the pick up reel 156 is, in turn, translated into a linear aft pulling force or tension on the deflecting component 30, to deflect the distal end of the guide tube 12.

The gear ratio of the rack 150 and the main gear 154, as well as the diameter of the main gear 154, are
30 selected, taking into account the size constraints imposed by the handle 14, to provide a desired mechanical advantage. The mechanical advantage amplifies the incremental amount of deflection of the deflection
35 component 30 for a given increment of rotation of the

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knob 26. Due to the mechanical advantage, the amount of manual, thumb-applied force required to rotate the knob 26 is, to the clinician, normal and without strain. Deflection of the guide tube 14 occurs with comfortable thumb control.

b. Pivot Tensioning System

Figs. 12 and 13 show an alternative arrangement for the steering assembly 24. The alternative arrangement shown in Figs. 12 and 13 shares many of the functional components of the arrangement shown in Fig. 8. Both include the rotary actuator knob 26 that carries the internal female threaded shaft 140, and a slider 142 that carries the threaded male component 146, which threadably engages the threaded shaft 140.

Also as before described, and as shown in Fig. 13, rotation of the actuator knob 26 is translated into linear movement of the slider 142 within the channel 144 inside the handle 14. In the rack and pinion linkage arrangement shown in Fig. 11, distal movement of the slider 144 (toward the knob 26) serves to apply tension to the deflecting component 30 through the rotation imparted to the take up reel 156 by the lateral movement of the rack 150 attached to the slider 144. In the alternative arrangement shown in Figs. 12 and 13, proximal movement of the slider 142 (away from the knob 26) applies tension to the deflection component 30 through a tension arm 160 that pivots in a proximal direction along the longitudinal axis of the handle 14. The deflecting component 30 is attached to the pivoting tension arm 160 and is placed into tension as a result of the proximal pivoting movement, to bend the distal region of the catheter tube 12, as Fig. 13 shows.

More particularly, the tension arm 160 is mounted on a pin 162 within the housing 14 for pivoting between a first pivot position, leaning distally toward the knob 26

- 18 -

(see Fig. 12) and a second pivot position leaning proximally away from the knob 26 (see Fig. 13). In the first pivot position (Fig. 12), no tension is applied to the deflecting component 30 attached to the tension arm 160. In the second pivot position (Fig. 13), the deflecting component 30 is placed into tension, to bend or deflect the distal end region of the guide tube 12.

When in the first pivot position (Fig. 12), the pivoting tension arm 160 rests against the proximal end of the slider 142. As the knob 26 is rotated in a predetermined direction (which, in the illustrated embodiment (Fig. 13), is counterclockwise from the standpoint of the clinician), the slider 142 is moved in a linear direction away from the knob 26. The slider 142 pushes against the tension arm 160, causing it to pivot about the pin 162 into the second pivot position. Pivoting of the tension element translates into a linear proximal pulling force or tension on the deflecting component 30, to deflect the distal end of the guide tube 12.

Translating the linear movement of the slider 142 into rotational movement of the pivoting tension arm 160 reduces the mechanical force advantage of the overall system, while increasing the amount of deflection of the distal end region per given rotation of the rotary control element.

3. The Deflection Component

The deflecting component 30 extends from the pick up reel 156 or pivoting tension arm 160 and into the control lumen 34 of the guide tube 12. The deflecting component 30 desirably comprises a strong and flexible material, e.g., metallic wire, braided metallic wire, monofilament wire, etc. In a preferred arrangement, the deflecting element 30 comprises a continuous length of braided polymer or natural fiber. The fiber extends from the pick

- 19 -

up reel 156 or pivoting tension arm 160, through the control lumen 34, looping completely around the tip reinforcing element 40, as Fig. 6B best shows. From there, the fiber extends back through the control lumen
5 34 to terminate at the pick up reel 156 or pivoting tension arm 160.

In this arrangement, the deflecting component 30 can be attached to the tip reinforcing element 40 by various methods, such as adhesion, welding techniques, soldering
10 techniques, tying or wrapping the deflection component 30 to the tip reinforcing element 40, or by forming the deflecting component 30 and the tip reinforcing element 40 as a composite structure. In the alternative embodiment shown in Fig. 6C, separate attachment means
15 may not be necessary to connect the deflecting component 30 to the tip reinforcing element 41.

II. USE OF STEERABLE GUIDE DEVICE

Fig. 14 shows the steerable guide device 10 in use to guide an operative tool 16 to a tissue site. In Fig.
20 14, the operative tool 16 takes the form of a powered device that applies a helical fastener 164. A representative embodiment of an endovascular device that, in use, applies a helical fastener is described in U.S. Patent Application 10/786,465, and entitled "Systems and
25 Methods for Attaching a Prosthesis Within a Body Lumen or Hollow Organ," which is incorporated herein by reference. In use (as Fig. 14 shows), the endovascular fastener device 16 is manipulated through the guide device 10 to apply one or more fasteners 164 to a prosthesis 166 that
30 is deployed to repair diseased and/or damaged sections of a hollow body organ and/or a blood vessel, e.g., to repair an aneurysm in the aorta in the region between the heart and the iliac bifurcation.

In use, the steerable guide device 10 is introduced
35 to the targeted tissue site through a conventional

- 20 -

intravascular approach. For example, when the targeted tissue site is in the aorta, the guide device 10 can be introduced through the femoral artery. However, other access sites and methods can be utilized. The guide
5 device 10 is desirably introduced over a guide wire, which extends through the passage 18. The guide wire can comprise the same guide wire over which the prosthesis 166 has been previously introduced, by means of a separately deployed prosthesis introducing tool. Or
10 alternatively, introduction of the steerable guide device 10 can be accomplished through a separate access site.

Upon withdrawal of the prosthesis introducing tool over the guide wire, and under fluoroscopic visualization, the clinician tracks the guide device 10
15 and dilator 60 over the same guide wire to locate the distal end region of the device 10 at or near the desired location with respect to the prosthesis. The guide wire and dilator 60 can now be withdrawn. Actuating the steering assembly 24 (by rotating the knob 26), and still
20 employing fluoroscopy visualization, the clinician deflects the distal end region of the device 10 -- and rotates the handle 14 to rotate the catheter tube 12, if necessary -- to orient the distal opening 22 of the passage 18 in a desired facing relationship with the site
25 where introduction of a fastener 164 is desired.

The operative tool 16, e.g., the endovascular fastener device, is now inserted through the proximal opening 20 and advanced through the passage 18 until the fastener 164 is located for deployment outside the now-
30 oriented distal opening 22, as Fig. 14 shows. The operative tool 16 can be actuated to apply a fastener 164 to the prosthesis 166. If the operative tool 16 is a single fire device, i.e., it carries only one fastener 164, the operative tool 16 is withdrawn through the
35 passage 18 and a new fastener 164 mounted. The distal end

- 21 -

region of the device 10 is reoriented in facing relationship with a new fastening site. The operative tool 16 is inserted back through the passage 18 to apply the second fastener to the new fastening site. This
5 sequence is repeated until a desired number and array of fasteners 164 are applied to the prosthesis 166. At this point, the guide device 10 can be withdrawn.

The foregoing is considered as illustrative only of the principles of the invention. Furthermore, since
10 numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described. While the preferred embodiment has been
described, the details may be changed without departing
15 from the invention, which is defined by the claims.

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We Claim:

1. A guide device comprising
a guide tube defining a guide passage through which
an operative tool can be deployed into an interior body
5 region, and
a steering assembly comprising a deflecting element
coupled to a distal end region of the guide tube to apply
a deflecting force to bend the distal end region, an
actuator, and a linkage system coupling the actuator to
10 the deflecting element to apply the deflecting force in
response to operation of the actuator, the linkage system
including a rack and a gear train coupled to the rack,
the linkage system being operative to translate rotation
of the actuator into linear movement of the rack into
15 rotation of the gear train to apply the deflecting force
to the deflecting component.
2. A device according to claim 1
further including a handle coupled to the guide
tube, and
20 wherein the linkage system is carried within the
handle.
3. A system comprising
a guide device as defined in claim 1, and
an operative tool that applies one or more fasteners
25 to tissue.
4. A method comprising
providing a guide device as defined in claim 1,
deploying the guide device into an interior tissue
region, and
30 operating the steering assembly to bend the distal
end region of the guide tube.
5. A method comprising
providing a system as defined in claim 3,
deploying the guide device into an interior tissue
35 region,

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operating the steering assembly to bend the distal end region of the guide tube,

passing the operative tool through the guide device, and

5 operating the operative tool while residing in the guide device to apply at least one fastener to tissue.

6. A guide device comprising

10 a guide tube defining a guide passage through which an operative tool can be deployed into an interior body region, and

15 a steering assembly comprising a deflecting element coupled to a distal end region of the guide tube to apply a deflecting force to bend the distal end region, an actuator, and a linkage system coupling the actuator to the deflecting element to apply the deflecting force in response to operation of the actuator, the linkage system including a slider and a pivoting lever arm coupled to the slider, the linkage system being operative to translate rotation of the actuator into linear movement of the slider into pivotal movement of the lever arm to apply the deflecting force to the deflecting component.

7. A device according to claim 6

25 further including a handle coupled to the guide tube, and

wherein the linkage system is carried within the handle.

8. A system comprising

a guide device as defined in claim 6, and

30 an operative tool that applies one or more fasteners to tissue.

9. A method comprising

providing a guide device as defined in claim 6,

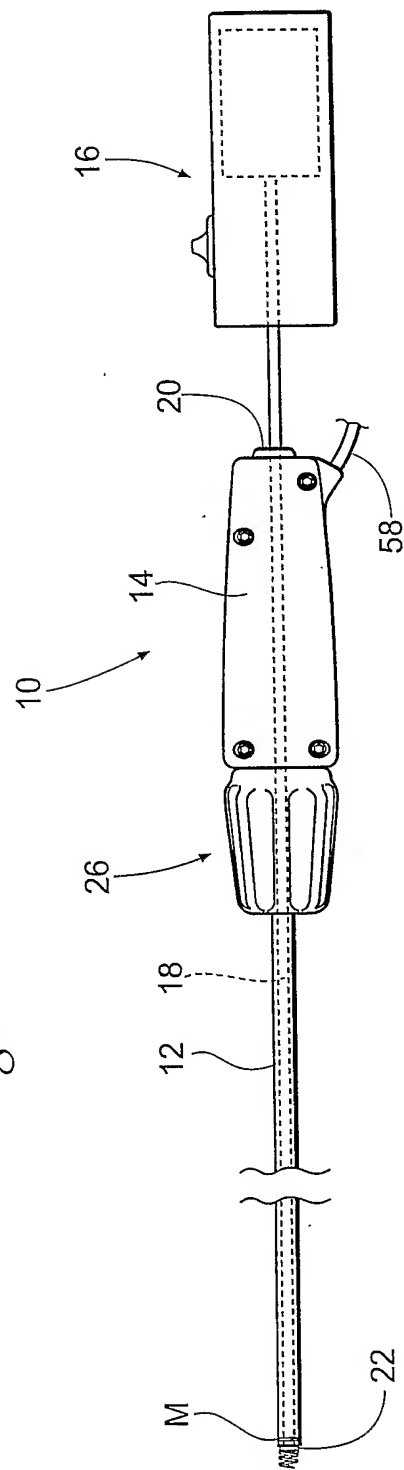
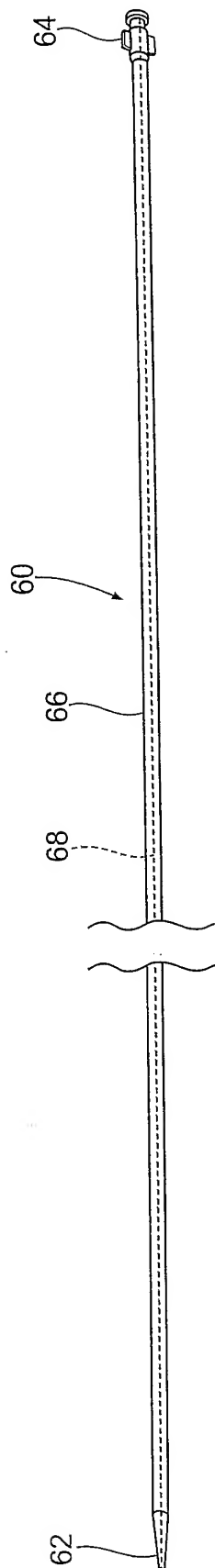
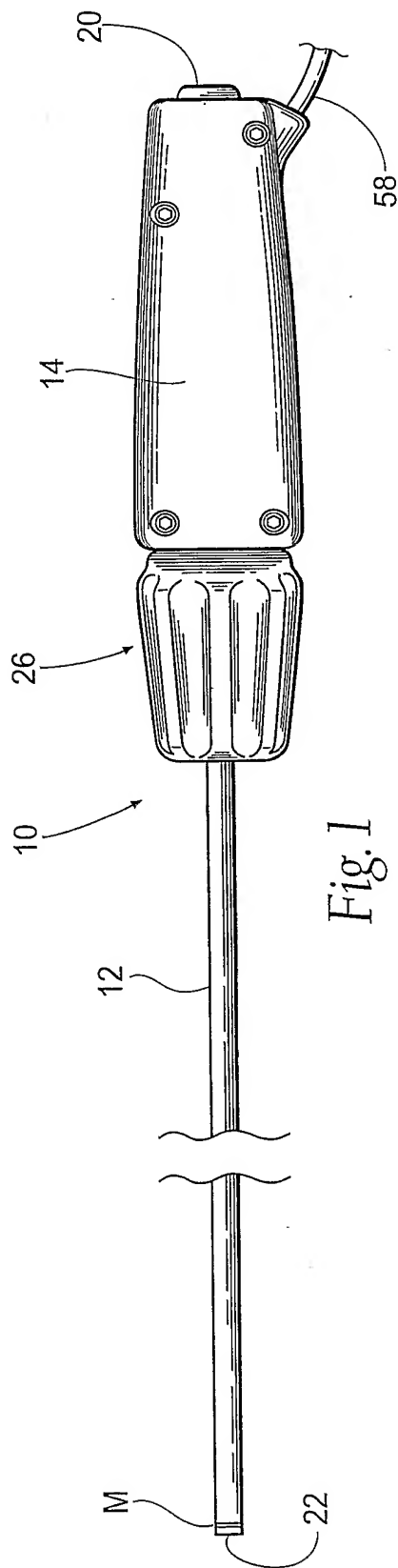
deploying the guide device into an interior tissue region, and

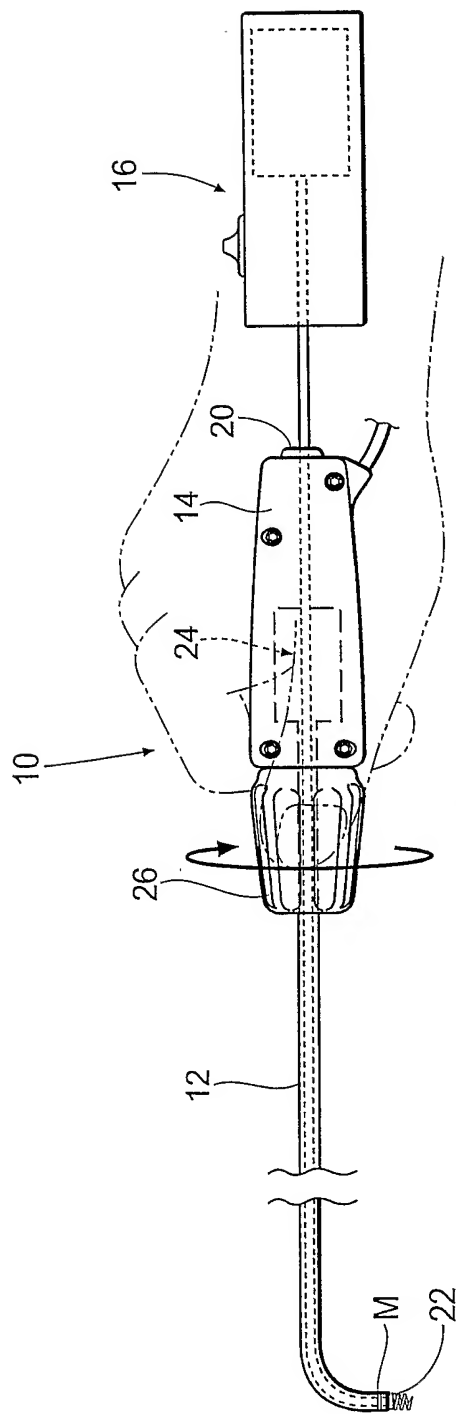
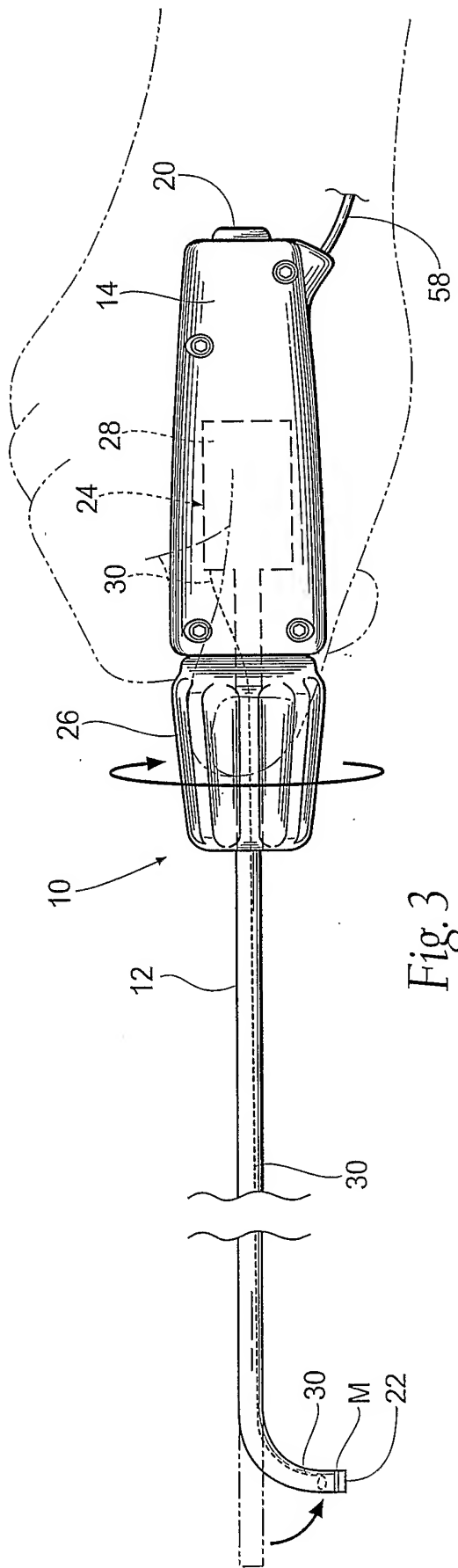
35 operating the steering assembly to bend the distal

- 24 -

end region of the guide tube.

10. A method comprising
providing a system as defined in claim 8,
deploying the guide device into an interior tissue
5 region,
operating the steering assembly to bend the distal
end region of the guide tube,
passing the operative tool through the guide device,
and
10 operating the operative tool while residing in the
guide device to apply at least one fastener to tissue.





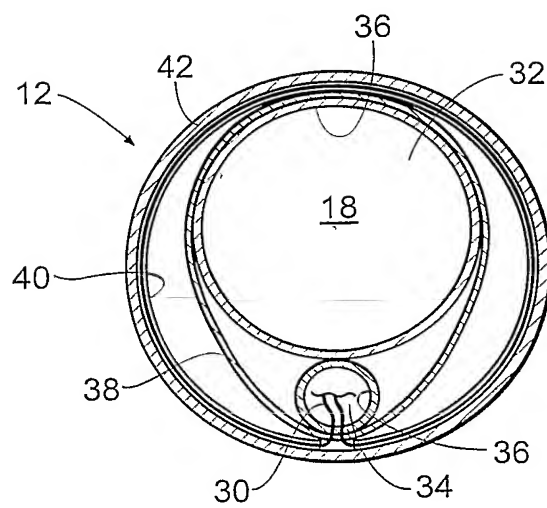
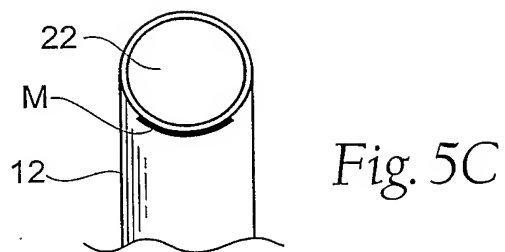
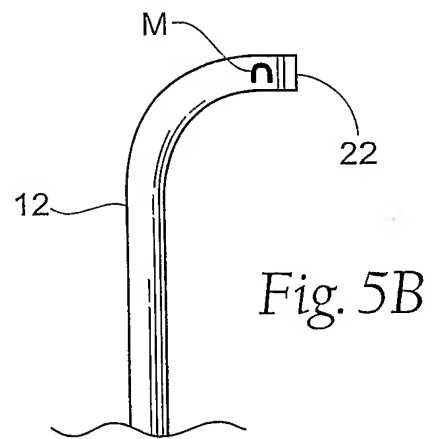
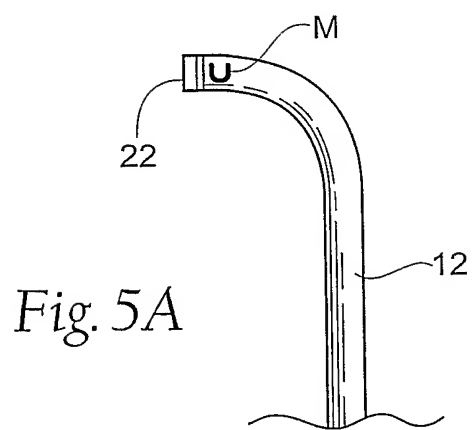


Fig. 6A

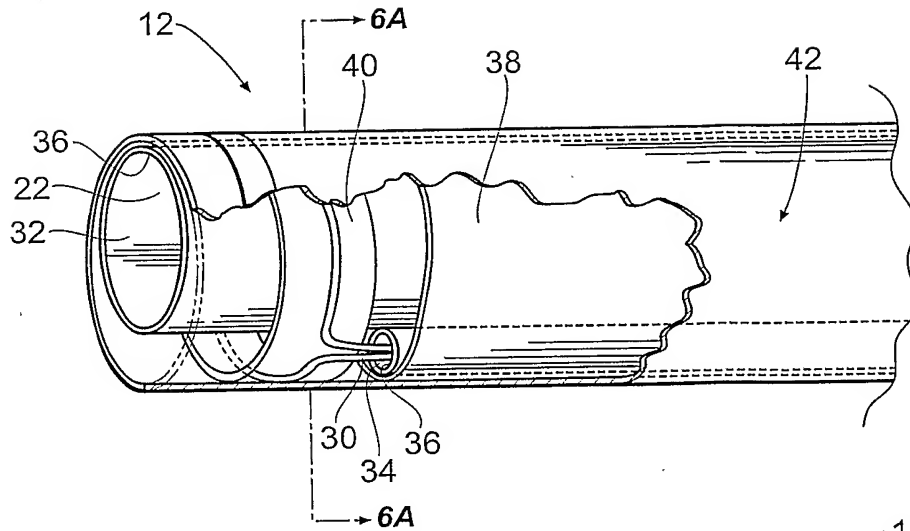


Fig. 6B

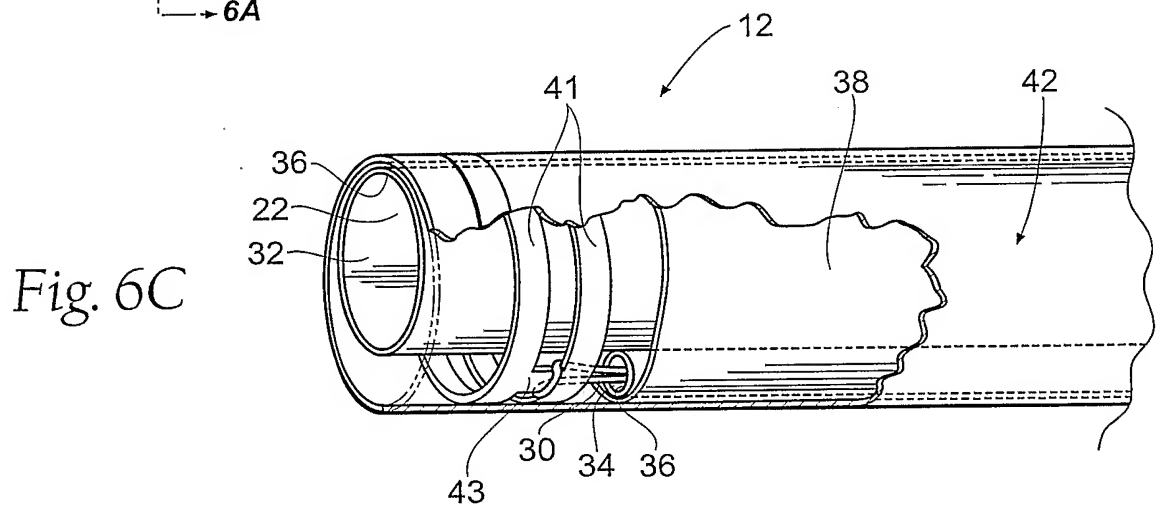


Fig. 6C

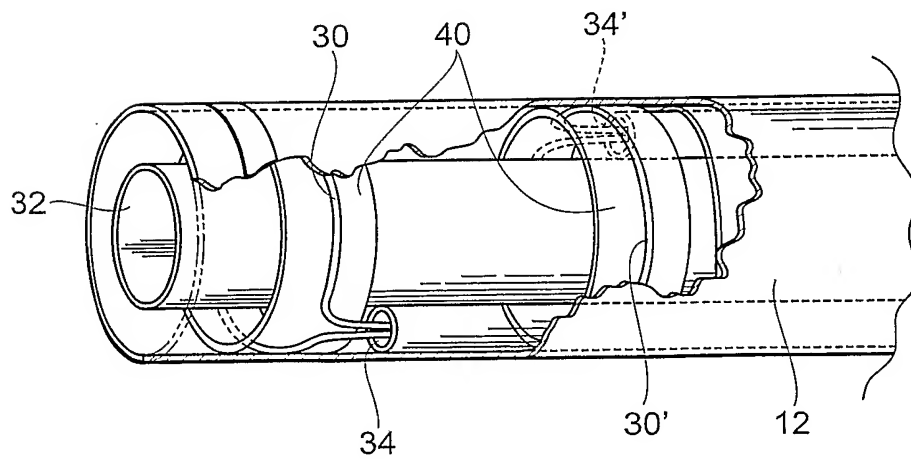


Fig. 6D

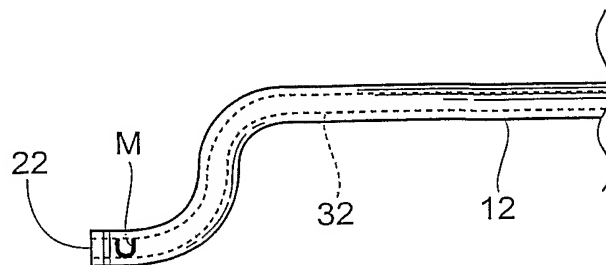
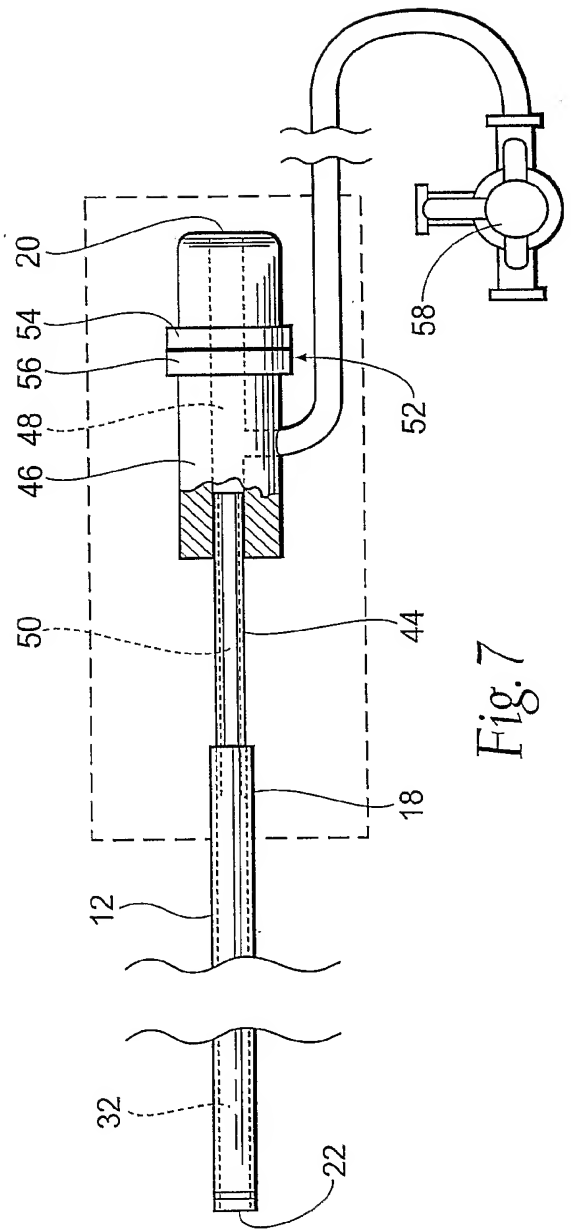
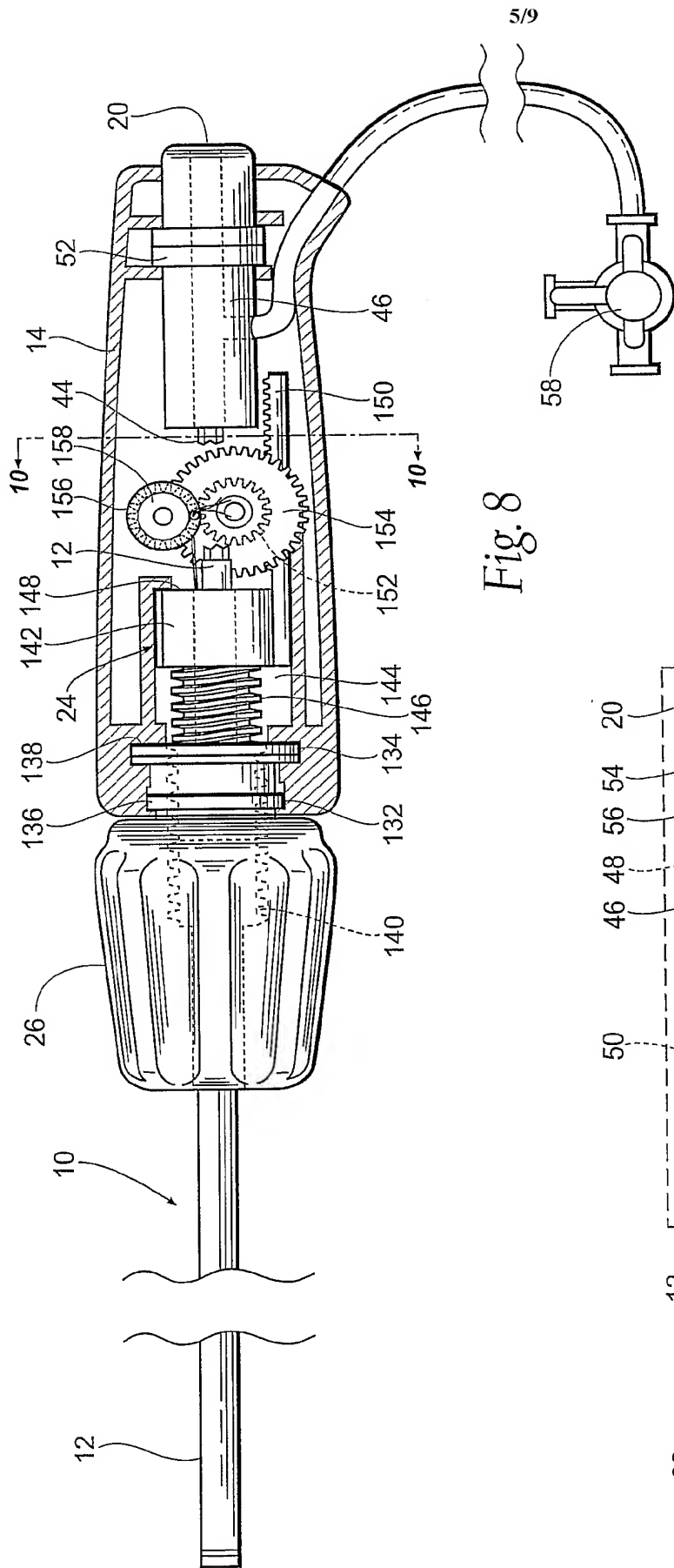


Fig. 6E



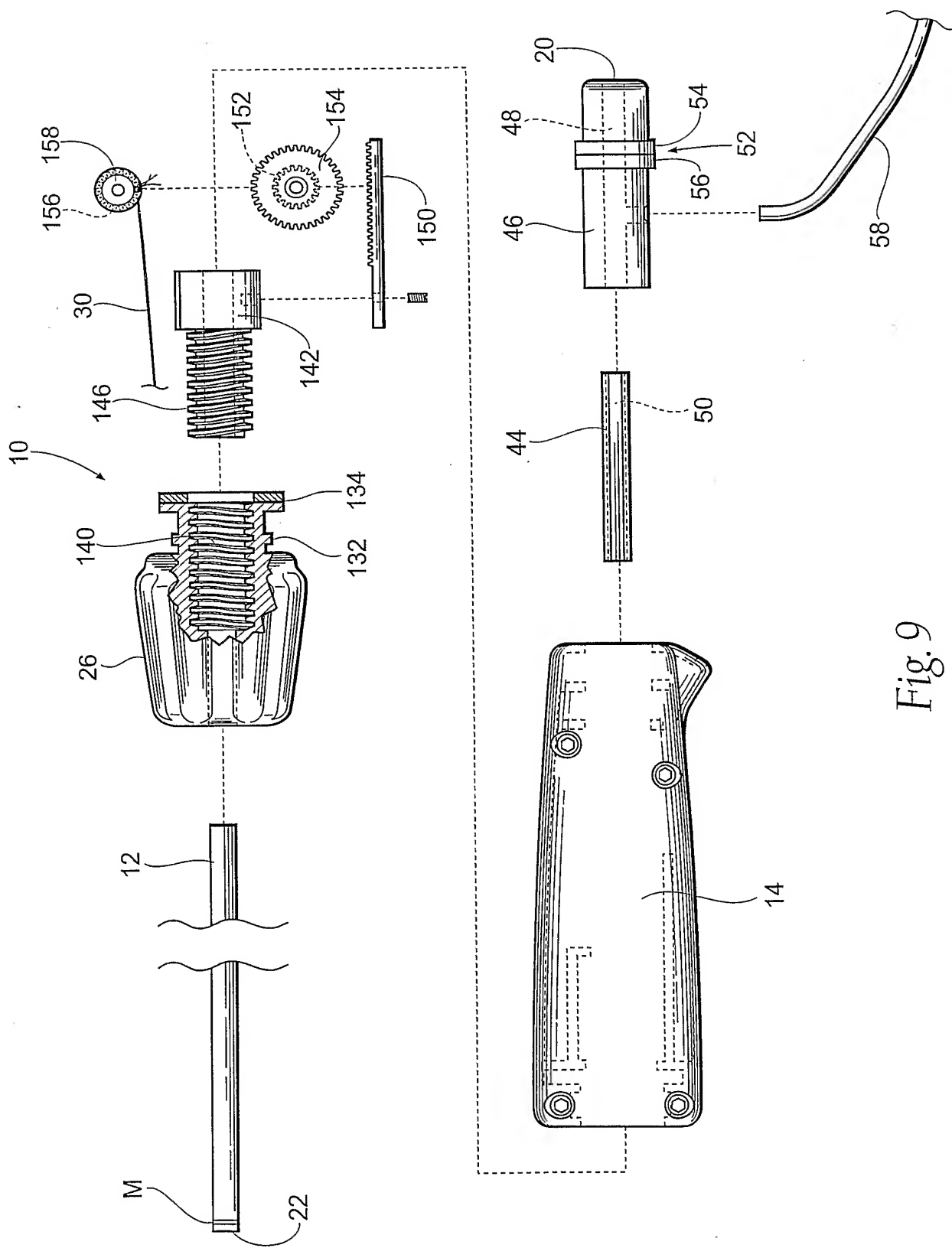
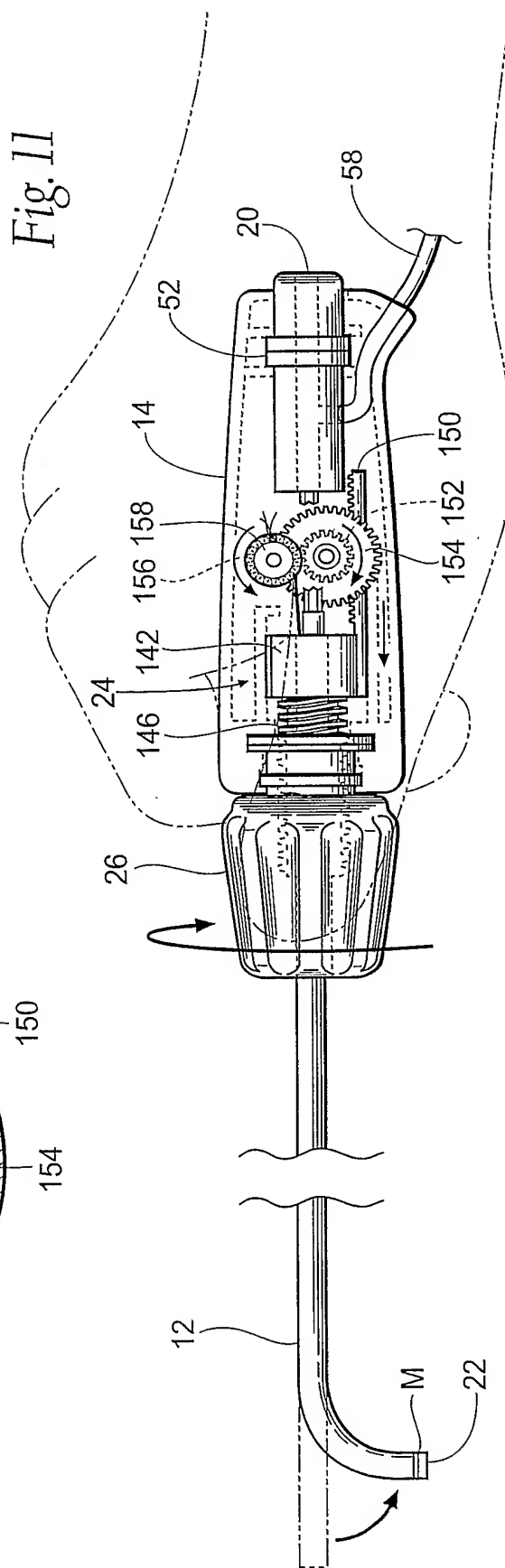
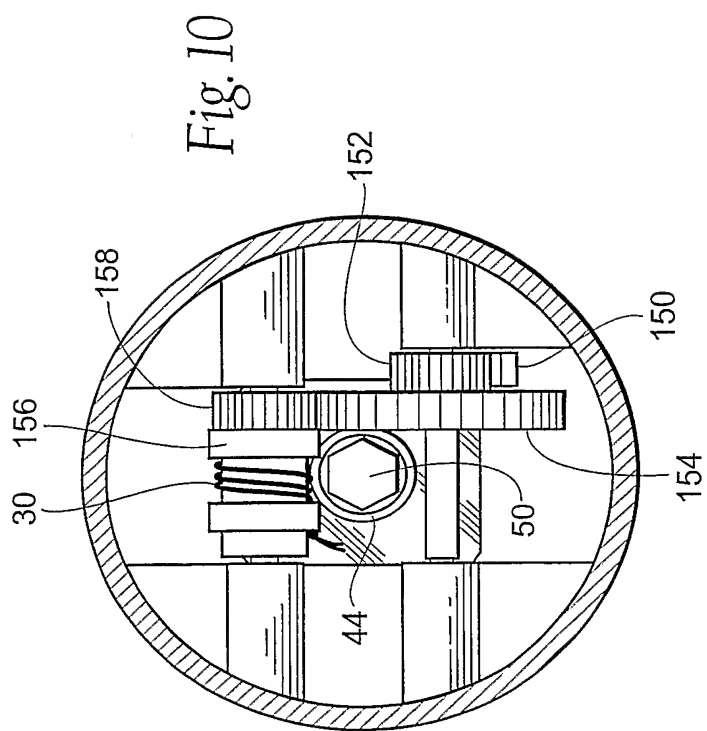
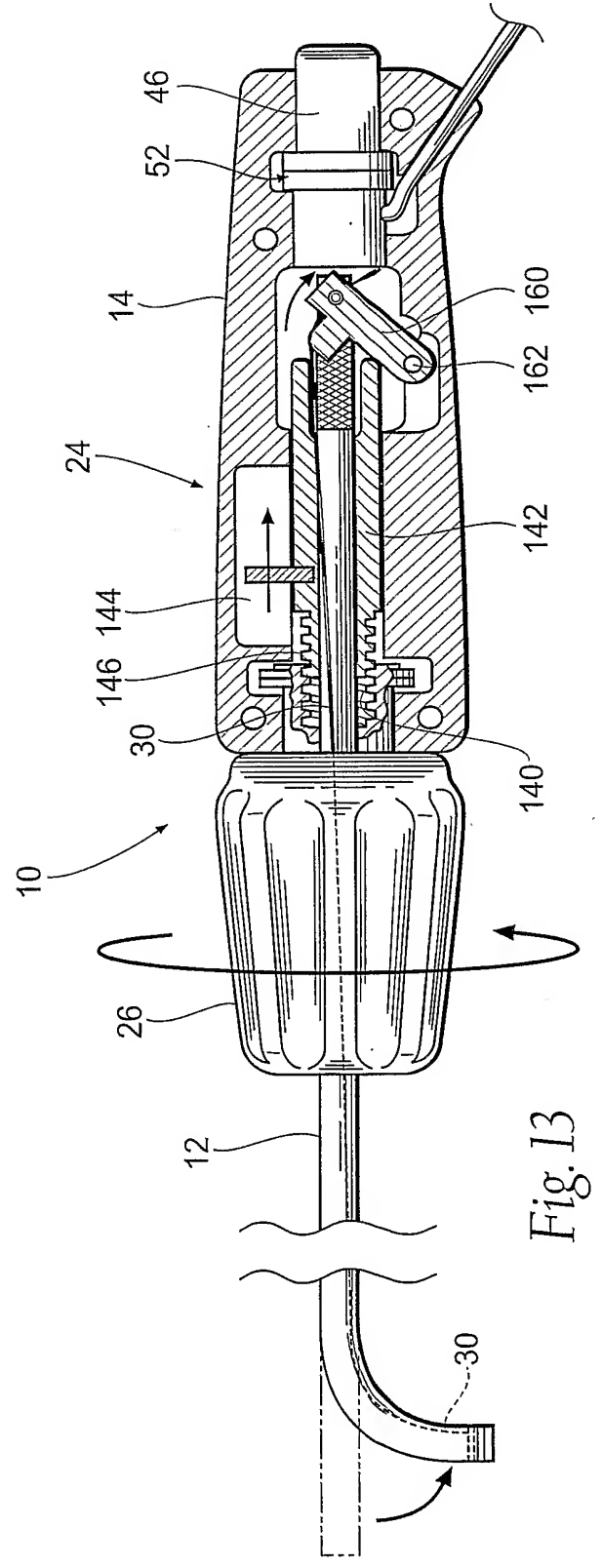
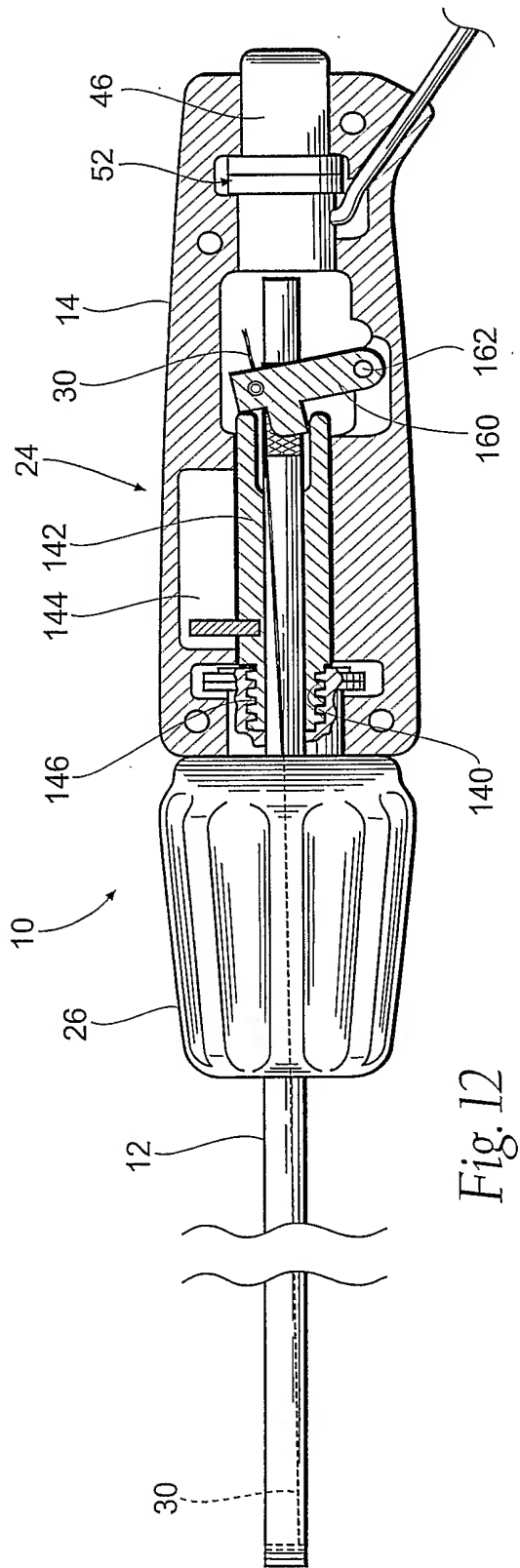


Fig. 9





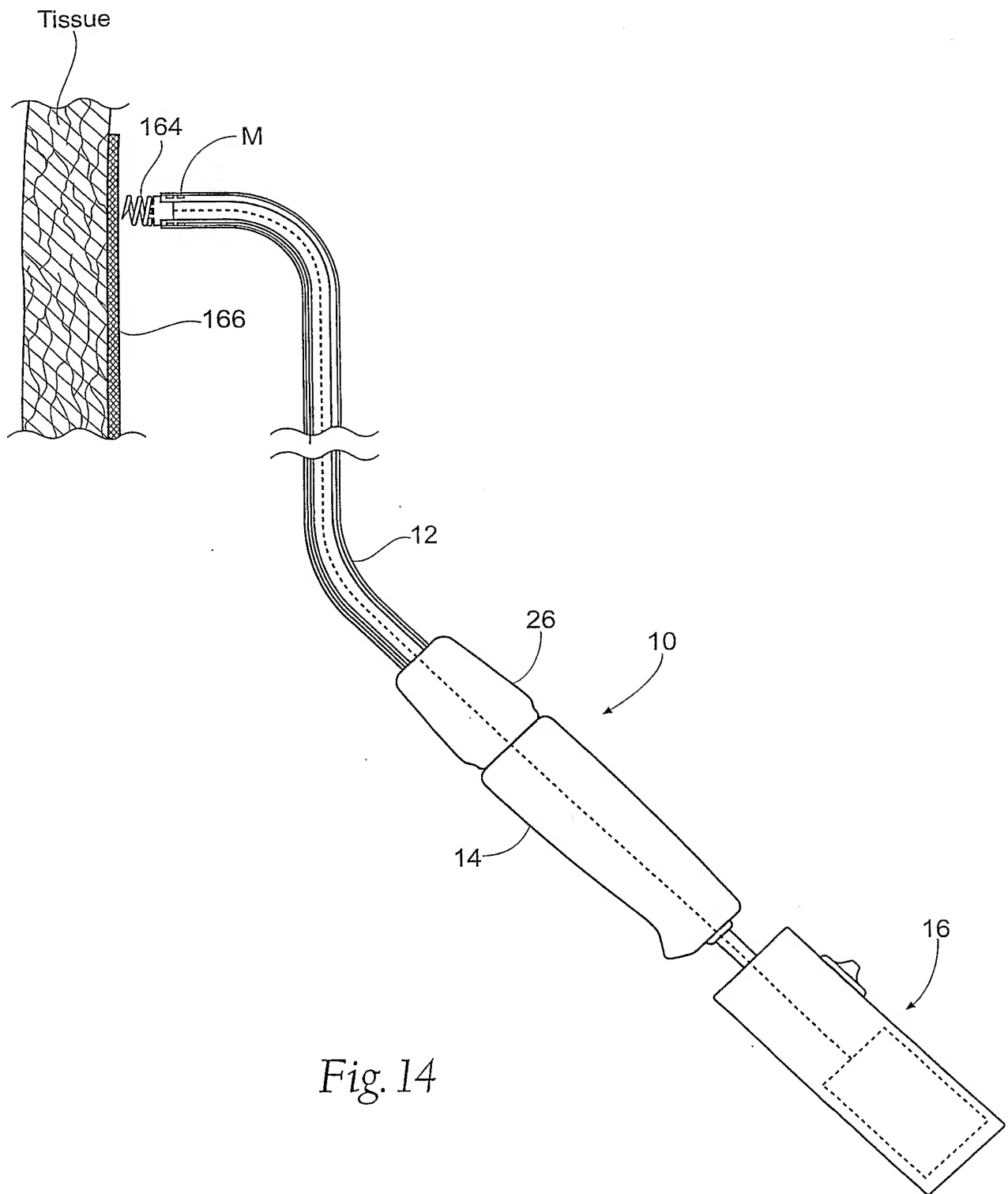


Fig. 14

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(74) Agents: **RYAN, Daniel, D.** et al.; P.O. Box 26618, Mil-
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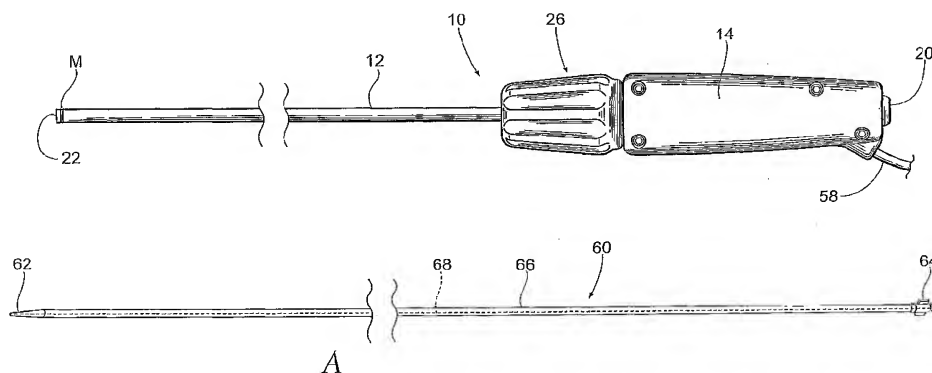
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(54) Title: DEVICES, SYSTEM, AND METHODS FOR GUIDING AN OPERATIVE TOOL INTO AN INTERIOR BODY RE-
GION



(57) Abstract: A guide device establishes a guide passage through a guide tube, through which an operative tool can be deployed into an interior body region for use. A steering assembly, in use, deflects or bends the distal end region of the guide tube, so that the operative tool can be placed in a desired orientation with respect to tissue. The steering assembly is desirably configured for single handed operation by the clinician. The steering assembly is also desirably configured to provide a mechanical advantage sufficient to translate relatively small increments of clinician control into relatively larger increments of guide tube deflection. In one arrangement, the steering assembly includes a rack and pinion linkage system. In another arrangement, the steering assembly includes a pivoting lever system.



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INTERNATIONAL SEARCH REPORT

International application No.

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A. CLASSIFICATION OF SUBJECT MATTER

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USPC - 606/108

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

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USPC - 606/108; 623/1.11, 1.23, 1.36

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

USPTO EAST System (US, USPG-PUB, EPO, DERWENT), MicroPatent

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,364,351 A (HEINZELMAN et al) 15 November 1994 (15.11.1994), whole document.	1-2, 4, 6-7, 9
Y		3, 5, 8, 10
Y	US 2003/0163085 A1 (TANNER et al) 28 August 2003 (28.08.2003), whole document.	3, 5, 8, 10
A	US 6,468,260 B1 (BUMBALOUGH et al) 22 October 2002 (22.10.2003), whole document.	1-10

☐ Further documents are listed in the continuation of Box C.

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Date of the actual completion of the international search

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Date of mailing of the international search report

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upon receipt of that report

For two-letter codes and other abbreviations, refer to the "Guid-
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ning of each regular issue of the PCT Gazette.

(54) Title: DEVICES, SYSTEMS, AND METHODS FOR PROSTHESIS DELIVERY AND IMPLANTATION, INCLUDING
THE USE OF A FASTENER TOOL

(57) Abstract: Devices, systems, and methods for implanting radially expandable prostheses in the body lumens rely on tacking or anchoring the prostheses with separately introduced fasteners. The prostheses may be self- expanding or balloon expandable, and may include a single lumen or more than one lumen. After initial placement, a fastener applier system is introduced within the expanded prostheses to deploy a plurality of fasteners to at least one prosthesis end. The fasteners are usually helical fasteners which are releasably restrained on the fastener driver, and are delivered by rotation of the fastener driver. The fasteners may be applied singly, typically in circumferentially spaced- apart patterns about the interior of at least one end of the prosthesis. A lumen extension or lumens may be coupled to the prosthesis to extend the reach of the prosthesis within the implantation site. Fasteners may also be applied to the lumen extensions .



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- 1 -

**DEVICES, SYSTEMS, AND METHODS FOR PROSTHESIS
DELIVERY AND IMPLANTATION, INCLUDING THE USE
OF A FASTENER TOOL**

Related Applications

5 This application is a continuation-in-part of co-
pending United States Patent Application Serial No.
11/254,619, filed October 20, 2005, and entitled
"Devices, Systems, and Methods for Guiding an Operative
Tool Into an Interior Body Region," which is incorporated
10 herein by reference. This application also is a
continuation-in-part of co-pending United States Patent
Application Serial No. 10/692,283, filed October 23,
2003, and entitled "Prosthesis Delivery Systems and
Methods," which claims the benefit of United States
15 Provisional Patent Application Serial No. 60/488,753,
filed July 21, 2003, and entitled "Endoprosthesis
Delivery Systems and Methods." This application also is a
continuation-in-part of co-pending United States Patent
Application Serial No. 10/786,465, filed February 25
20 2004, and entitled "Systems and Methods for Attaching a
Prosthesis Within a Body Lumen or Hollow Organ." This
application is also a continuation-in-part of co-pending
United States Patent Application 11/693,255, filed June
24, 2005, entitled "Multi-Lumen Prosthesis Systems and
25 Methods," which is a division of United States Patent

- 2 -

Application Serial No. 10/693,255, filed 24 October 2003 (now United States Patent 6,929,661), which claims the benefit of United States Provisional Patent Application Serial No. 60/489,011, filed July 21, 2003, and entitled

5 "Bifurcated Prosthesis Systems and Methods." This application also is a continuation-in-part of co-pending United States Patent Application Serial No. 10/307,226, filed 29 November 2002, and entitled "Intraluminal Prosthesis Attachment Systems and Methods." This

10 application is also a continuation-in-part of copending United States Patent Application Serial Number 10/669,881, entitled "Catheter-Based Fastener Implantation Apparatus and Methods with Implantation Force Resolution." This application is also a

15 continuation-in-part of copending United States Patent Application Serial No. 11/166,411, filed June 24, 2005, entitled "Endovascular Aneurysm Repair System," which is a division of United States Patent Application Serial No. 10/271,334, filed 15 October 2002 (now United States

20 Patent No. 6,960,217), which claims the benefit of United States Provisional Patent Application Serial No. 60/333,937, filed 28 November 2001, and entitled "Endovascular Aneurysm Repair System." Each of the preceding applications is incorporated herein by

25 reference.

Field of the Invention

The invention relates generally to devices, systems, and methods for the delivery and implantation of a prosthesis to a targeted site within the body, e.g., for

30 the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel.

Background of the Invention

The weakening of a vessel wall from damage or disease can lead to vessel dilatation and the formation

35 of an aneurysm. Left untreated, an aneurysm can grow in

- 3 -

size and may eventually rupture.

For example, aneurysms of the aorta primarily occur in the abdominal region, usually in the infrarenal area between the renal arteries and the aortic bifurcation.

5 Aneurysms can also occur in the thoracic region between the aortic arch and renal arteries. The rupture of an aortic aneurysm results in massive hemorrhaging and has a high rate of mortality.

Open surgical replacement of a diseased or damaged
10 section of vessel can eliminate the risk of vessel rupture. In this procedure, the diseased or damaged section of vessel is removed and a prosthetic prosthesis, made either in a straight or bifurcated configuration, is installed and then permanently attached and sealed to the
15 ends of the native vessel by suture. The prosthetic prosthesis for these procedures are usually unsupported woven tubes and are typically made from polyester, ePTFE or other suitable materials. The prosthesis are longitudinally unsupported so they can accommodate
20 changes in the morphology of the aneurysm and native vessel. However, these procedures require a large surgical incision and have a high rate of morbidity and mortality. In addition, many patients are unsuitable for this type of major surgery due to other co-morbidities.

25 Endovascular aneurysm repair has been introduced to overcome the problems associated with open surgical repair. The aneurysm is bridged with a vascular prosthesis, which is placed intraluminally. Typically these prosthetic prostheses for aortic aneurysms are
30 delivered collapsed on a catheter through the femoral artery. These prostheses are usually designed with a fabric material attached to a metallic scaffolding (stent) structure, which expands or is expanded to contact the internal diameter of the vessel. Unlike open
35 surgical aneurysm repair, intraluminally deployed

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prostheses are not sutured to the native vessel, but rely on either barbs extending from the stent, which penetrate into the native vessel during deployment, or the radial expansion force of the stent itself, is utilized to hold the prosthesis in position. These prosthesis attachment means do not provide the same level of attachment when compared to suture and can damage the native vessel upon deployment.

Accordingly, there is a need for improved prosthesis delivery devices, systems, and methods that deliver a prosthetic graft to a body lumen, the prosthesis being able to adapt to changes in aneurysm morphology and able to be deployed safely and without damage to the native vessel.

Summary of the Invention

The devices, systems, and methods for delivering and implanting radially expandable prostheses in the body lumens are described. In particular, the present invention provides improved devices, systems, and methods for implanting vascular prostheses into blood vessels, including both arterial and venous systems. In the exemplary embodiments, prostheses are placed in vasculature to reinforce aneurysms, particularly abdominal aortic aneurysms.

One aspect of the invention provides devices, systems, and methods for fastening a prosthesis into a hollow body organ or blood vessel. The devices, systems, and methods include a fastener applier that is sized and configured for securing a prosthesis, the fastener applier comprising a handle assembly positioned at the caudal end of the fastener applier, a fastener applier shaft coupled to the handle assembly, and a fastener driver for advancing a fastener into the prosthesis and tissue, the fastener driver coupled to the fastener applier shaft at the cephalad end of the fastener applier

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shaft, the fastener driver including a housing and a release latch, wherein the release latch prevents premature release of the fastener from the fastener driver. The fastener driver housing may also include an internally threaded portion and a non-threaded portion, the non-threaded portion providing an area where the fastener can be rotated but not advanced out of the driver, the advancement out of the driver only taking place if the fastener has been previously engaged in tissue or the prosthesis.

In one embodiment, the handle assembly may further include a motion control assembly to be used by an operator, the motion control assembly providing motion control of the fastener within the fastener driver. The motion control assembly may include a forward control function and a reverse control function. The handle assembly may also include an indication assembly to provide information to an operator, the indication assembly providing at least one of an audible and visual indication. The information provided may include at least one of a fastener position or timing or status or error, or any combination.

In one embodiment, fastener is a helical fastener. The helical fastener may include a fastener body having a distal end for penetrating tissue in response to a force and a proximal end for releasably coupling the fastener body to the fastener applier, and a stop structure associated with the proximal end to prevent over-penetration of the fastener body into tissue, the stop structure bisecting the diameter of the fastener body. The stop structure may be offset from the diameter of the fastener body.

An additional aspect of the invention provides devices, systems, and methods for storing a fastener used for securing a prosthesis into a hollow body organ or

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blood vessel. The devices, systems, and methods comprise a base structure, and at least one receptacle positioned within the base structure, the receptacle sized and configured to releasably store at least one fastener. The
5 receptacle may be sized and configured to releasably store at least one helical fastener. The helical fastener may include a fastener body having a distal end for penetrating tissue in response to a force and a proximal end for releasably coupling the fastener body to the
10 fastener applier, and a stop structure associated with the proximal end to prevent over-penetration of the fastener body into tissue, the stop structure bisecting the diameter of the fastener body. The stop structure may be offset from the diameter of the fastener body.

15 In one embodiment the receptacle is sized and configured to present the fastener to a fastener applier. There may also be a post positioned within the receptacle to releasably restrain the fastener. A pliable material may also be included within the receptacle to position a
20 tip of the fastener in the pliable material to releasably restrain the fastener. The fastener may also be releasably restrained within the receptacle by friction between the fastener and the receptacle wall.

Yet an additional aspect of the invention provides
25 devices, systems, and methods for installing a fastener to a fastener applier used for securing a prosthesis into a hollow body organ or blood vessel. The devices, systems, and methods comprise providing an apparatus for storing a fastener, the apparatus comprising a base
30 structure, and at least one receptacle positioned within the base structure, the receptacle sized and configured to releasably store at least one fastener, providing a fastener applier for securing a prosthesis, the fastener applier comprising a handle assembly positioned at the
35 caudal end of the fastener applier, a fastener applier

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shaft coupled to the handle assembly, and a fastener driver for advancing a fastener into the prosthesis and tissue, the fastener driver coupled to the fastener applier shaft at the cephalad end of the fastener applier shaft, the fastener driver including a housing and a release latch, wherein the release latch prevents premature release of the fastener from the fastener driver, positioning the fastener driver so as to allow the fastener driver to couple to releasably stored fastener, and coupling the fastener to the fastener applier. The step of coupling the fastener to the fastener applier may also include operating a motion control assembly positioned on the handle assembly to retract the fastener out of the receptacle and onto the fastener driver.

In one embodiment, the receptacle is sized and configured to releasably secure at least one helical fastener. The helical fastener may include a fastener body having a distal end for penetrating tissue in response to a force and a proximal end for releasably coupling the fastener body to the fastener applier, and a stop structure associated with the proximal end to prevent over-penetration of the fastener body into tissue, the stop structure bisecting the diameter of the fastener body. The stop structure may be offset from the diameter of the fastener body.

Other features and advantages of the invention shall be apparent based upon the accompanying description, drawings, and claims.

Brief Description of the Drawings

Fig. 1 is a perspective view of one embodiment of a prosthesis deployment catheter shown positioned within an abdominal aortic aneurysm.

Fig. 2 is a perspective view of one embodiment of the deployment of a prosthesis within the aneurysm of

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Fig. 1, with the jacket partially retracted.

Fig. 3 is a perspective view of one embodiment of the deployment of a prosthesis within the aneurysm of Fig. 1, with the jacket fully retracted and showing radial expansion of the proximal end.

Fig. 4 is a perspective view of one embodiment of the completed deployment of a multi-lumen prosthesis within the aneurysm of Fig. 1.

Fig. 5 is a perspective view of an alternative embodiment of the completed deployment of a single lumen prosthesis within the aneurysm of Fig. 1.

Fig. 6 is a side view of the multi-lumen prosthesis assembly that embodies features of the invention, the multi-lumen prosthesis assembly shown with lumen extensions.

Fig. 7A is a side view of the main body component of the multi-lumen prosthesis assembly.

Fig. 7B is an enlarged view showing detail of the distal stent curved apices of the multi-lumen prosthesis shown in Fig. 7A.

Fig. 7C is a side view of one embodiment of the prosthesis septum, showing stitches and weaving to form the septum.

Fig. 7D is a side view of an alternative embodiment of the main body component of the multi-lumen prosthesis assembly of Fig. 7A, showing the main body prosthesis having a second lumen extending beyond the first lumen.

Fig. 8A is a section view of the distal end of the main body component of the multi-lumen prosthesis taken generally along line 8A-8A of Fig. 6.

Fig. 8B is a section view of the proximal end of the main body component of the multi-lumen prosthesis taken generally along line 8B-8B of Fig. 6.

Fig. 9A is a side view of a prosthesis lumen extension.

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Fig. 9B is an enlarged view showing detail of the securing stent curved apices of the lumen extension shown in Fig. 9A.

5 Fig. 9C is a side view of one extension lumen coupled to the main body component of the multi-lumen prosthesis.

10 Fig. 9D is an enlarged view showing detail of the curved apices of both the securing stent of the lumen extension coupled to the distal stent of the main body prosthesis, as shown in Fig. 9C.

Fig. 10A is a side view of an alternative embodiment of the prosthesis lumen extension of Fig. 9A, and shows securing stents without deflected apices.

15 Fig. 10B is an enlarged view showing detail of the securing stents of the lumen extension shown in Fig. 10A.

Fig. 10C is a side view showing the alternative embodiment of the prosthesis lumen extension of Fig. 10A coupled to the main body component of the multi-lumen prosthesis.

20 Fig. 10D is an enlarged view showing detail of the securing stents of the alternative embodiment of the lumen extension coupled to the distal stent of the main body prosthesis, as shown in Fig. 10C.

25 Fig. 11 is a perspective view of a prosthesis deployment catheter that embodies features of the invention.

Fig. 12 is a side view of one embodiment of the proximal end of the deployment catheter of Fig. 11.

30 Fig. 13 is a side view of the proximal end of the deployment catheter of Fig. 11, and showing a jacket covering components of the deployment catheter.

Fig. 14A is a side view of the proximal end of the deployment catheter of Fig. 11, and showing the jacket covering the main body component of the multi-lumen prosthesis prior to deployment.

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Fig. 14B is a perspective view of an alternative embodiment of the deployment catheter jacket of Fig. 11 showing structural reinforcement.

5 Fig. 15 is a section view of the lumens in the central shaft deployment catheter taken generally along line 15-15 of Fig. 12.

Fig. 16 is a side view of the catheter tip and central shaft of the deployment catheter showing the catheter tip lumen and central shaft lumen.

10 Fig. 17 is a perspective view of the main body component of the multi-lumen prosthesis positioned on the proximal end of the deployment catheter prior to deployment, and showing the first proximal retaining means in a compressed condition.

15 Fig. 18A is a side view of one embodiment of a suture loop path around the main body component of the multi-lumen prosthesis.

20 Fig. 18B is a side view of an alternative embodiment of a suture loop path around the multi-lumen prosthesis of Fig. 18A, showing multiple suture loops.

25 Fig. 19 is a perspective view of the main body component of the multi-lumen prosthesis positioned on the proximal end of the deployment catheter showing the first proximal retaining means released and the proximal end of the main body component expanded.

Fig. 20 is a side view of a portion of the distal end of the deployment catheter showing one embodiment of a first proximal releasing means and a first proximal release wire.

30 Fig. 21 is a side view of a portion of the proximal end of the deployment catheter showing detail of the first proximal release hub and central shaft lumens.

35 Fig. 22 is a side view of a portion of the distal end of the deployment catheter showing detail of one embodiment of the second proximal releasing means.

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Fig. 23 is a side view showing detail of the stabilizing arms in a pre-deployment configuration, the proximal ends of the stabilizing arms being arched back generally toward a first proximal release hub.

5 Fig. 24 is a side view of the stabilizing arms of Fig. 23 in a pre-deployment configuration with the deployment catheter and multi-lumen prosthesis positioned within the descending aorta, and showing the proximal ends of the stabilizing arms coupled to the proximal end
10 of the main body prosthesis.

Fig. 25 is a side view showing detail of stabilizing arms coupled to the proximal end of the main body prosthesis, showing the second proximal release wire stitched or otherwise extended through a stabilizing arm
15 aperture and through the prosthesis material, releasably securing the stabilizing arms to the main body prosthesis.

Fig. 26 is a side view of the stabilizing arms of Fig. 23 in a post-deployment configuration with the
20 deployment catheter and multi-lumen prosthesis positioned within the descending aorta, and showing the proximal ends of the stabilizing arms released from the proximal end of the main body prosthesis.

Fig. 27 is a section view of the proximal end of the
25 deployment catheter shaft taken generally along line 27-27 of Fig. 23.

Fig. 28 is a side view of the distal end of the main body prosthesis positioned on the deployment catheter central shaft prior to deployment of the distal retaining
30 means.

Fig. 29A is a side view of one embodiment of a suture loop path around the distal end of the multi-lumen prosthesis.

Fig. 29B is a side view of an alternative embodiment
35 of a suture loop path around the distal end of the multi-

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lumen prosthesis of Fig. 29A, showing multiple suture loops.

Fig. 30 is a side view of the distal end of the main body component of the multi-lumen prosthesis positioned on the deployment catheter shaft of Fig. 28, showing the distal retaining means released and the distal end of the main body component expanded.

Fig. 31 is a side view of a portion of the proximal end of the deployment catheter showing detail of the distal releasing means and central shaft lumens.

Fig. 32 is a side view of an alternative embodiment of the distal end of the main body prosthesis positioned on the deployment catheter central shaft prior to deployment of the distal retaining means.

Fig. 33 is a side view of the distal end of the main body component of the multi-lumen prosthesis positioned on the deployment catheter shaft of Fig. 32, showing the alternative distal retaining means released and the distal end of the main body component expanded.

Fig. 34 is a perspective view of a first side of the deployment catheter handle assembly that embodies features of the invention.

Fig. 35 is a perspective view of a second side of the deployment catheter handle assembly that embodies features of the invention.

Fig. 36 is a top view of the deployment catheter handle assembly of Fig. 34.

Fig. 37 is a section view of the deployment catheter handle assembly of Fig. 34 taken generally along line 37-37 of Fig. 36.

Fig. 38 is a section view of the deployment catheter handle assembly of Fig. 34 taken generally along line 38-38 of Fig. 36.

Fig. 39 is a top view of a portion of the deployment catheter handle assembly of Fig. 34 showing the jacket

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retraction means prior to jacket retraction.

Fig. 40 is a top view of a portion of the deployment catheter handle assembly of Fig. 39 showing the jacket retraction means after the jacket has been retracted.

5 Fig. 41 is a perspective view of a second side of one embodiment of a rack and pinion mechanism and a release system positioned within the deployment catheter handle assembly.

10 Fig. 42 is a perspective view of a second side of one embodiment of a rack and pinion mechanism and a release system positioned within the deployment catheter handle assembly.

15 Fig. 43 is a perspective view showing detail of the release system positioned within the deployment catheter handle assembly.

Fig. 44A is a perspective view of a lumen extension deployment catheter that embodies features of the invention.

20 Fig. 44B is a perspective view of the lumen extension deployment catheter shown in Fig. 44A, and showing a stationary outer jacket and a hemostatic valve.

Fig. 45A is a side view of one embodiment of the proximal end of the lumen extension deployment catheter of Fig. 44.

25 Fig. 45B is a side view of an alternative embodiment of the proximal end of the lumen extension deployment catheter of Fig. 45A, and shows an optional distal retaining and releasing means.

30 Fig. 46A is a side view of a proximal section of the lumen extension deployment catheter of Fig. 45A, and showing a jacket covering the lumen extension positioned on the catheter shaft prior to deployment.

35 Fig. 46B is a side view of an alternative embodiment of a proximal section of the lumen extension deployment catheter of Fig. 45B, and showing a jacket covering the

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lumen extension positioned on the catheter shaft prior to deployment and including a distal retaining means.

Fig. 46C is a perspective view of an alternative embodiment of the lumen extension deployment catheter jacket of Fig. 44 showing structural reinforcement.

Fig. 47A is a section view of the lumen extension deployment catheter shaft of Fig. 45A taken generally along line 47A-47A of Fig. 45A.

Fig. 47B is a section view of an alternative embodiment of the lumen extension deployment catheter shaft of Fig. 45B taken generally along line 47B-47B of Fig. 45B.

Fig. 48A is a side view of one embodiment of a suture loop path around the proximal end of the lumen extension.

Fig. 48B is a side view of one embodiment of a suture loop path around the distal end of the lumen extension.

Fig. 48C is a side view of an alternative embodiment of a suture loop path around the proximal or distal end of the lumen extension shown in Figs. 48A and 48B, and shows multiple suture loops.

Fig. 49A is side view of the lumen extension deployment catheter handle assembly of Fig. 44.

Fig. 49B is a side view of an alternative embodiment of the lumen extension deployment catheter handle assembly of Fig. 44, and showing an additional slide knob for an optional distal releasing means.

Fig. 50 is top view of the lumen extension deployment catheter handle assembly of Fig. 44.

Fig. 51 is a perspective view of one embodiment of the release system positioned within the handle assembly of the lumen extension deployment catheter.

Fig. 52 is an enlarged perspective view of one embodiment of a helical fastener that can be used in

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association with a fastener tool or device shown in Fig. 53.

Fig. 53 is a perspective view of a fastener tool that embodies features of the invention.

5 Fig. 54 is a perspective view of the handle assembly of the fastener tool of Fig. 53.

Fig. 55 is a perspective view of a steerable guide device that embodies features of the invention.

10 Fig. 56 is a perspective view of the handle assembly of the steerable guide device of Fig. 55.

Fig. 57 is a perspective view of an obturator or dilator that may be used in conjunction with the steerable guide device of Fig. 55.

15 Fig. 58 is a perspective view of one embodiment of a prosthesis deployment catheter shown positioned within an abdominal aortic aneurysm.

20 Fig. 59 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, with the jacket partially retracted.

25 Fig. 60 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, with the jacket fully retracted but prior to the release of the proximal or distal retaining means.

30 Fig. 61 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, with the jacket fully retracted but prior to the release of the proximal or distal retaining means and showing an alternative embodiment of the distal retaining means.

35 Fig. 62 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the first proximal retaining means released and the proximal end of

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the main body component expanded.

Fig. 63 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing a second
5 guide wire positioned through the main body prosthesis lumen.

Fig. 64 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the steerable
10 guide and obturator positioned on the second guide wire and through the main body prosthesis lumen.

Fig. 65 is an enlarged perspective view of the deployment of the main body component of the multi-lumen prosthesis within the descending aorta, and showing the
15 steerable guide device and the fastener tool just prior to fastening a helical fastener through the prosthesis material and into tissue.

Fig. 66 is an enlarged perspective view of the deployment of the main body component of the multi-lumen
20 prosthesis within the descending aorta, and showing the steerable guide device and the fastener tool just after fastening a helical fastener through the prosthesis material and into tissue.

Fig. 67 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis
25 within the aneurysm of Fig. 58, and showing the deflected end of the steerable guide device and the fastener tool after being repositioned for deployment of an additional helical fastener.

Fig. 68 is an enlarged perspective view of the deployment of the main body component of the multi-lumen prosthesis within the descending aorta, and showing one
30 embodiment of a fastener deployment pattern.

Fig. 69 is a perspective view of the deployment of a
35 lumen extension component of the multi-lumen prosthesis

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within the aneurysm of Fig. 58, and showing the lumen extension catheter being positioned partially within a prosthesis lumen.

5 Fig. 70 is a perspective view of the deployment of the lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the jacket retracted from the lumen extension deployment catheter and prior to the release of a proximal retaining means.

10 Fig. 71 is a perspective view of the deployment of the lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the lumen extension coupled to and fully expanded within a lumen of the main body component after the release of
15 the proximal retaining means.

Fig. 72 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the lumen extension deployment catheter removed and the stabilizing
20 arms of the main body deployment catheter released.

Fig. 73 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the distal retaining means released and the distal end of the main
25 body prosthesis expanded.

Fig. 74 is a perspective view of the deployment of the main body component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the withdrawal of the rejacketed main body deployment
30 catheter over the first guide wire.

Fig. 75 is a perspective view of the deployment of a second lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the lumen extension catheter being positioned partially
35 within a prosthesis lumen.

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Fig. 76 is a perspective view of the deployment of the second lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the jacket retracted from the lumen extension deployment catheter and prior to the release of a proximal retaining means.

Fig. 77 is a perspective view of the deployment of the second lumen extension component of the multi-lumen prosthesis within the aneurysm of Fig. 58, and showing the second lumen extension coupled to and fully expanded within a lumen of the main body component after the release of the proximal retaining means.

Fig. 78 is a perspective view of one embodiment of the completed deployment of the multi-lumen prosthesis within the aneurysm of Fig. 58.

Fig. 79A is an enlarged perspective view of an alternative embodiment of a helical fastener that can be used in association with a fastener tool or device shown in Fig. 53.

Fig. 79B is an enlarged top view of the alternative fastener of Fig. 79A showing a "D" shape.

Fig. 80 is an enlarged perspective view of the deployment of the main body component of the multi-lumen prosthesis within the descending aorta, and showing the steerable guide device and the fastener tool having an alternative fastener driver just prior to fastening the helical fastener of Fig. 79A through the prosthesis material and into tissue.

Fig. 81 is an enlarged perspective view of the fastener driver and fastener of Fig. 80, and showing the fastener rotating off of the fastener carrier.

Fig. 82A is an enlarged side view of the fastener driver of Fig. 80, and showing a fastener positioned on the fastener carrier and within a threaded fastener housing, and also showing the fastener latch feature.

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Fig. 82B is an enlarged side view of the fastener driver of Fig. 80, and showing a fastener on the carrier and rotating off the carrier and showing the pivoting of the fastener latch.

5 Fig. 82C is an enlarged side view of the fastener driver of Fig. 80, and showing a fastener positioned on the fastener carrier and within a threaded fastener housing, and also showing an alternative fastener latch feature.

10 Fig. 83 is a perspective view of one embodiment of a fastener cassette with fasteners releasably positioned with a fastener receptacle.

Fig. 84 is a perspective view of an alternative embodiment of a fastener cassette of Fig. 82.

15 Fig. 85 is a perspective view showing the fastener tool positioned on a fastener cassette for removal of a fastener from the cassette and positioning the fastener within the fastener driver.

Fig. 86 is a perspective view showing the fastener tool with a fastener positioned in the fastener driver and ready for deployment.

Detailed Description of the Invention

This Specification discloses various catheter-based devices, systems, and methods for delivering and
25 implanting radially expandable prostheses in the body lumens. For example, the various aspects of the invention have application in procedures requiring the repair of diseased and/or damaged sections of a hollow body organ and/or blood vessel. The devices, systems, and methods
30 that embody features of the invention are also adaptable for use with systems and surgical techniques that are not necessarily catheter-based.

The devices, systems, and methods are particularly well suited for treating aneurysms of the aorta that
35 primarily occur in the abdominal region, usually in the

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infrarenal area between the renal arteries and the aortic bifurcation, as well as aneurysms that also occur in the thoracic region between the aortic arch and renal arteries. For this reason, the devices, systems, and methods will be described in this context. Still, it should be appreciated that the disclosed devices, systems, and methods are applicable for use in treating other dysfunctions elsewhere in the body, which are not necessarily aorta-related.

10 I. OVERVIEW

Fig. 1 depicts a portion of the descending aorta and shows an abdominal aortic aneurysm 20. For the purposes of illustration, Fig. 1 shows the targeted site for delivery and implantation of a prosthesis as being within the abdominal aortic aneurysm 20. It is to be appreciated that the targeted site can also be elsewhere in the body. In the illustrated arrangement, the prosthesis takes the form of an endovascular graft.

In order to provide a consistent orientation for the devices, systems, and methods described herein, the terms proximal or cephalad will be used to describe a relation or orientation toward the head or heart, and the terms distal or caudal will be used to describe a position or orientation toward the feet or away from the heart. Therefore, the devices, systems, and methods can be described as having a proximal or cephalad component and a distal or caudal component. The use of these terms also applies to the implantation apparatus as used in the implantation process described, i.e., the deployment catheter handle is distal or caudal as the handle of the deployment catheter is oriented toward the feet and away from the heart.

The proximal or cephalad end 202 of a prosthesis deployment catheter 200 can be seen in Fig. 1 positioned over a first guide wire 30 (the guide wire being

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previously positioned) and extending through at least a portion of the abdominal aortic aneurysm 20. The deployment catheter 200 carries the main body of the prosthesis 120 (see Fig. 2), which is placed at the targeted site, e.g., by radial expansion of the main body prosthesis 120 (see Fig. 3). After expansion of the main body prosthesis 120, one or more fasteners 402 (see Fig. 4) may be introduced by a fastener device 400 to anchor the proximal end 108 of the main body prosthesis, in place.

Fig. 2 depicts the initial stage of the main body prosthesis 120 deployment at the targeted site. While the deployment method can vary, in the illustrated embodiment, the delivery catheter 200 has a movable jacket or outer sheath 210, which overlays the main body prosthesis 120. When the outer jacket 210 is pulled distally, or in a caudal direction, the main body prosthesis 120 is exposed but may remain in an undeployed configuration until releasing means has been activated. Once the releasing means has been activated, the main body prosthesis or a portion(s) of the main body prosthesis 120 is free to radially expand, thereby enlarging to contact at least a portion of the internal walls of the blood vessel. The prosthesis deployment process is continued, including the deployment of one or more lumen extensions, until a multi-lumen or bifurcated prosthesis 100 is fully deployed within the vessel, as can be seen in Fig. 4 and will be described in greater detail later.

It is to be understood that the terms prosthesis and prostheses both can mean an independent component, or multiple components coupled together, or multiple components not necessarily coupled together. The prosthesis may be either coupled together at or near the targeted site, or exterior the body, or a combination of

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both.

In a desirable embodiment, the prosthesis is a multi-lumen prosthesis. In an alternative embodiment, the prosthesis is a straight prosthesis. The prosthesis 100
5 may be self-expanding, or, the prosthesis 100 can utilize an expanding member, such as a balloon or mechanical expander. Fig. 4 depicts a completely deployed multi-lumen or bifurcated prosthesis 100 that is sized and configured to be positioned within the aorta and extend
10 across the aneurysm and into the contralateral iliac artery and the ipsilateral iliac artery. Fig. 5 depicts a completely deployed straight prosthesis 50.

It is to be appreciated that one or more fasteners 402 can be introduced into the multi-lumen prosthesis 100
15 to anchor the main body 120 and/or lumen extensions 140 in place at different times or at the same time during the procedure.

II. GENERAL METHODS OF ENDOVASCULAR IMPLANTATION

The prosthesis or prostheses 100 as just described
20 lend themselves to implantation in a hollow organ in various ways. The prosthesis may be implanted using catheter-based technology via a peripheral intravascular access site, such as in the femoral artery, optionally with the assistance of image guidance. Image guidance
25 includes but is not limited to fluoroscopy, ultrasound, magnetic resonance, computed tomography, or combinations thereof. Alternatively, the prosthesis can be implanted, e.g., in an open chest surgical procedure.

Figs. 58 to 78 show a representative embodiment of
30 the deployment of a prosthesis of the type shown in Fig. 4 by a percutaneous, catheter-based procedure. Percutaneous vascular access is achieved by conventional methods into the femoral artery, for example.

The implantation of the multi-lumen prosthesis 100
35 is first described here in a number of general steps. The

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multi-lumen prosthesis and each of the various tools used to implant the prosthesis are then described with additional detail below. The multi-lumen prosthesis 100 is described in section III and the various implantation apparatus are described in section IV. Additionally, the
5 general implantation steps are then described again with additional detail below in section V.

A first implantation step can be generally described as deploying the main body 120 of the prosthesis. The
10 deployment catheter 200 is positioned within the aortic aneurysm 20 and the main body of the prosthesis is allowed to deploy. Proximal and distal retaining means hold the main body prosthesis in a predetermined relationship to the proximal end 202 of the deployment
15 catheter. By activating a proximal releasing means, the proximal end 108 of the main body prosthesis 120 may be partially or fully released from the deployment catheter shaft so as to allow the proximal stent 130 to expand to contact the aorta or a portion of the aorta. At this step
20 the prosthesis may not be fully released from the deployment catheter. The main body prosthesis 120 may be attached to the deployment catheter 200 through a second proximal retaining means. The proximal end 108 or other areas of the main body prosthesis 120 is fastened to the
25 vessel wall to resist axial migration of the prosthesis.

Next, an extension catheter 350 carrying a first prosthesis lumen extension 140 is guided through the vasculature and to the main body prosthesis 120. The first lumen extension is telescopically fitted within the
30 second lumen 128 of the main body prosthesis 120 and allowed to radially expand. The extension catheter is then removed, leaving the lumen extension 140 coupled to the main body prosthesis 120 and extending into the contralateral iliac artery.

35 If the main body prosthesis 120 is attached to the

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deployment catheter 200 through a second proximal retaining means, a second releasing means is activated to allow the proximal end 108 of the main body prosthesis 120 to release from the deployment catheter shaft 216.

5 The distal releasing means is then activated, allowing the distal end 110 of the main body prosthesis 120 to release from the deployment catheter shaft 216 and radially expand. The deployment catheter 200 is then removed from the body.

10 Lastly, the extension catheter 350 carrying a second prosthesis, lumen extension 140 is guided through the vasculature and to the main body prosthesis 120. The second lumen extension 140 is telescopically fitted within the first lumen 126 of the main body prosthesis
15 and allowed to radially expand. The extension catheter 350 is then removed, leaving the lumen extension 140 coupled to the main body prosthesis 120 and extending into the ipsilateral iliac artery. The multi-lumen prosthesis 100 is now fully deployed across the aortic
20 aneurysm.

III. MULTI-LUMEN PROSTHESIS ASSEMBLY

Fig. 6 shows a multi-lumen prosthesis assembly 100 that embodies features of the invention. In the illustrated embodiment, the multi-lumen prosthesis
25 assembly 100 comprises a main body component 120 and at least one lumen extension 140, desirably two lumen extensions.

The main body component 120 is sized and configured to fit within a hollow body organ and/or a blood vessel.
30 As described in this Specification, the targeted site of deployment is within the aorta adjacent the renal arteries, as will be described in greater detail later. However, this targeted site of deployment is selected for purposes of illustrating the features of the prosthesis
35 100, and is not intended to be limiting.

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Referring to Fig. 7A, the main body component 120 has a proximal and distal end 108, 110, and includes an interior communicating with a proximal opening 122 for fluid flow into or from the prosthesis. The main body component 120 includes a septum 124 within its interior. The length of the septum 124 within the prosthesis 120 can vary. In the illustrated embodiment, the septum 124 does not extend along the entire length of the main body component 120, but is spaced a distance from the proximal opening 122. In the illustrated arrangement, the septum 124 comprises a longitudinal seam. The seam can be formed by coupling the opposing surfaces together (i.e., the front and back) of the prosthesis material 112 (which is typically a fabric) by sewing, heat bonding, stitching or weaving, for example, or any combination. The coupling of the opposing surfaces together thereby creates a septum or shared, common wall between two lumens, the first lumen 126 and the second lumen 128 (see Figs. 8A and 8B). Typically the seam 124 would be located along the midline of the main body to create two equally sized lumens 126 and 128. However, the location of the seam 124 could be moved, if different sized lumens were desired. In one embodiment shown in Fig. 7C, the septum 124 is formed by a stitch(s) 131 at the septum's proximal end 121, a stitch(s) 133 at the septum's distal end 123, and a weave(s) 135 in-between the stitches 131, 133 at the septum's proximal end 121 and distal end 123. The combination of stitches and weaving, for example, provides added stability to the septum 124.

The septum 124 transforms at least a portion of the interior of the main body component 120 into the multi-lumen flow channel configuration. In the illustrated embodiment, the multi-lumen flow channel configuration comprises dual first and second interior lumens 126 and 128. Due to the septum 124, the dual first and second

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interior lumens 126 and 128 of the multi-lumen flow channel configuration do not form branched or divergent lumens. The shared common wall or seam (the septum 124) prevents divergence and maintains the lumens 126 and 128 in a non-divergent, generally parallel flow relationship (as Figs. 8A and 8B show).

In the illustrated arrangement, the septum 124 runs generally along the mid-line of the main body component 120, making the multi-lumen flow channel configuration within the main body component 120 essentially symmetric. However, it should be appreciated that the septum 124 could form a non-symmetric multi-lumen flow channel configuration. It should also be appreciated that multiple septums can be present within the interior, transforming the interior of the main body component 120 into several flow lumens. The length of the septum can vary. In a representative embodiment, the septum 124 is typically greater than 10 mm in length and not less than 5 mm in length.

In the illustrated embodiment, the first lumen 126 defines a flow channel sized and configured to reach a targeted destination or source spaced a defined distance from the proximal opening 122, while the truncated second lumen 128 communicates with generally the same targeted destination as the proximal opening 122 of the main body component 120 itself. Furthermore, the septum 124 is sized and configured to accommodate the coupling of a flow channel extension 140 to the first lumen 126 and to the truncated second lumen 128, to likewise extend their reach to another targeted source or destination spaced from the proximal opening 122, if desired.

The second lumen 128 is truncated along at least a portion of the septum 124. As a result, the distal opening 127 of the first lumen 126 can be said to extend beyond the distal opening 129 of the second lumen 128.

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Still, the shared common wall (the septum 124) prevents divergence and maintains the lumens 126 and 128 in a non-divergent, generally parallel flow relationship. It is to be appreciated that the first and second lumens 126, 128
5 may be reversed, i.e., the second lumen 128 may extend beyond the first lumen 126 (see Fig. 7D).

In this arrangement, the multi-lumen prosthesis assembly 100 desirably includes a first and second flow channel lumen extension 140 (see Fig. 6). The first and
10 second lumen extensions 140 desirably comprise the same construction, i.e., they are duplicates of each other. Referring to Fig. 9A, the lumen extension 140 includes a proximal end 142 that is sized and configured to be telescopically fitted within the first lumen 126 and/or
15 the truncated second lumen 128 of the main body component 120. The distal end 144 of the lumen extension 140 is sized and configured to extend the reach of the first lumen 126 and the truncated second lumen 128 to another targeted destination or source spaced a defined distance
20 from the main body component proximal opening 122. As a result, a portion of the extended second lumen 128 is joined to the first lumen 126 by the septum 124, and a portion of the extended second lumen 128 is not joined by the septum 124 to the lumen extension 140 of the first
25 lumen 126.

Both the first lumen 126 and the truncated second lumen 128 of the main body component 120, which is joined by the septum 124 to the first lumen 126, provide an interface region or socket that is fully enclosed within
30 the body of the main body component 120 itself. The first lumen 126 and the truncated second lumen 128 are therefore not prone to kinking or twisting or other kinds of movement independent of the main body component 120. Passage of a guide wire through the first lumen 126 or
35 the second lumen 128 can occur unimpeded.

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Being telescopically fitted within the interface region or socket and enclosed within the main body component 120, the mechanical properties of the lumen extension 140 are supplemented by the structural support and integrity of the main body component 120 itself, and vice versa. Coupled together, the main body component 120 and the lumen extension 140 provide enhanced resistance to migration and/or separation of the lumen extension 140 from the main body component 120. Seated within the enclosed interface region, the lumen extension 140 is peripherally sealed within the main body component 120 to resist leaks or seepage of fluids around the lumen extension 140. The septum 124 can be tapered, curved, wavy, or otherwise non-linear to enhance the connection between the lumen extension 140 and the main body component 120.

In one illustrated use (see Fig. 3), the main body component 120 can be deployed in the aorta in the region of the bifurcation of the first and second iliac, or ipsilateral and contralateral iliac arteries. When the main body prosthesis 120 is deployed, both the first lumen 126 and the second lumen 128 remains in communication with the aorta. After the main body component 120 is deployed, the first lumen extension 140 can be fitted within the distal opening 127 of the first lumen 126, and the second lumen extension 140 can be fitted within the distal opening 129 of the second lumen 128, so that the distal end 144 of the first extension 140 can be sized to reach into the first iliac of the bifurcation, while the distal end 144 of the second extension 140 can reach into the second iliac of the bifurcation (see Fig. 4). In this arrangement, the first lumen extension 140 of lumen 126 serves as a first lumen or ipsilateral lumen of the prosthesis 100, and the lumen extension 140 of the second lumen 128 serves as a second

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lumen or contralateral lumen.

The main body component 120 may include a proximal sealing stent 130 at its proximal end 108, which may extend beyond the prosthetic material 112 (see Fig. 7A).

5 The proximal stent 130 orients the main body prosthesis 120 within the lumen and aids in maintaining the position of the main body prosthesis 120 in the aorta without obstructing the normal blood flow into the renal arteries. The proximal sealing stent 130 may be a self-
10 expanding zigzag or diamond shaped stent, for example, and is desirably sewn inside the prosthesis material 112, although the stent may be outside, or may be wrapped between two layers of prosthesis material 112, for example.

15 Typically, this region of the aorta (proximal neck of the aneurysm just below the renal arteries) is also one area where one or more fasteners 402 may be introduced by a fastener device 400 to anchor the prosthesis 100 in place (see Fig. 4). However, it should
20 be noted that other areas throughout the main body 120 and lumen extensions 140 can also be fastened in place. It is desirable that this region of the main body component 120 be sized and configured for the receipt and retention of fasteners, e.g., the size and spacing of
25 diamond or zigzag stent patterns to specially accommodate the placement of fasteners; and/or the use of woven fibers with an "X-pattern" or a "sinusoidal pattern" to specially accommodate placement of fasteners; and/or to fold over the prosthetic material 112 to form multiple
30 layers, to reinforce the prosthesis in the region where fasteners 402 are placed; and/or the use of denser weave patterns or stronger fibers from, e.g., Kevlar™ material or Vectran™ material or metallic wire woven alone or interwoven with typical polyester fibers in the region
35 were fasteners are placed. It may also be desirable to

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fluoroscopically indicate this region of the prosthesis with radiopaque markers 132 on the prosthetic material 112 or proximal sealing stents 130 to aid in positioning the fastening devices.

5 Additional stents may be utilized throughout the main body component 120. Desirably, a minimal number of stents would be utilized within the main body component 120.

10 The multiple lumens 126 and 128 in the main body component 120 may typically be supported with distal stent rings 134 sewn or otherwise attached to the inside or outside of the prosthetic material 112. The proximal apices 136 of the stent rings 134 desirably are angled or curved inwardly (see Fig. 7B). The inward angle provides
15 a retentive feature when the lumen extension 140 is positioned within a first or second lumen (see Fig. 10B). Alternative retentive features may also be used, such as hooks, barbs, loops of fabric or loops/folds of graft material or pockets in graft material, for example.
20 Ideally, the distal stent rings 134 in one lumen 126 are staggered axially in position with the stent rings 134 in the other lumen 128, so that they do not overlap each other when the main body component 120 is radially compressed prior to deployment.

25 Rotational orientation of the main body component 120 within the vessel lumen or hollow body organ is accomplished with additional radiopaque markers 137 and 138 attached to the main body prosthesis 120 for visualization under fluoroscopy. Typically, these markers
30 may be attached to the prosthetic material 112. Still, the markers 137 and 138 may be attached to the proximal sealing stent 130 or distal stent rings 134 instead of or in addition to the prosthetic material 112 to help fluoroscopically determine the location of all prosthesis
35 openings. The radiopaque markers typically are in the

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form of marker bands, tight wound coils, or wire made from radiopaque materials such as platinum, platinum/iridium, tantalum, or gold for example.

Desirably, one or more markers 137, 138, are longer
5 than the other, and are attached on opposite sides of the main body component 120 with the longer markers 137 aligned on the side with the first lumen 126 and the shorter markers 138 aligned on the side with the second lumen 128, for example. In an alternative embodiment the
10 markers could be aligned with the septum. The markers 137 and 138 enable the clinician to determine the desired rotational orientation of the main body prosthesis 120 in the delivery system so that, upon deployment, the first distal opening 127 and the second distal opening 128 are
15 aligned with the desired iliac arteries. The proximal markers 132 may also be included to enable the clinician to determine the position of the proximal end 108 of the main body component 120 in relation to the fixation point of the aorta. Additionally, distal markers 139 may be
20 included to aid in the location of the distal openings 127, 129, and the insertion of the lumen extension 140. Insertion depth marker(s) 125 may be attached near the septum 124, or may be attached to the septum, or may be attached to the prosthesis material 112, for example, to
25 indicate the location of and insertion depth for the lumen extension 140.

As previously described, the main body 120 (and the lumen extension 140) desirably utilizes a prosthetic material 112. The material 112 of the main body 120 may
30 carry individual self-expanding, zigzag or diamond type stent rings, for example. The stent rings need not be attached to one another throughout the main body prosthesis 120. However, it may be desirable in certain locations within the prosthesis structure 120 to have
35 attachments between the individual stent rings to provide

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stability and/or additional radial support.

As previously stated, the septum 124 is formed by sewing, heat bonding, stitching, or weaving opposing surfaces (i.e., the front and back) of the prosthetic material 112 of the main body component 120 together. In the region of the septum 124, the stent rings 134 extend from the septum 124 about the formed lumen, but do not enter or otherwise interrupt the septum 124 itself. The septum 124 is continuous and is formed separate from the supporting structure of stent rings 134.

The individual distal stent rings 134 allow for longitudinal main body prosthesis 120 compliance while maintaining radial support of the prosthesis lumens. This technical feature allows the prosthesis to more readily accommodate changes in vessel/aneurysm morphology.

The stents can be made, e.g., from Nitinol®. Still, other materials, manufacturing methods and designs can be used. Each of the stents may be sewn onto prosthetic material 112. In certain locations it is desired to have the stents attached to the outer diameter of the prosthetic material 112. Still, it is also contemplated that the stents could be attached to the inner diameter of the prosthetic material 112.

In the illustrated embodiment, the prosthetic material 112 is woven polyester, and the attachment of the stents is made with polyester suture. However, it is also contemplated that other attachment means could be utilized to secure the stents to the prosthetic material 112. These means include bonding; capturing the stents between two layers of prosthetic material 112; and incorporating the stents directly into the woven prosthetic material 112.

As seen in Fig. 9A, the lumen extension 140 has at least one spiral stent 146 positioned along at least a portion of the length of the extension and attached to

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the outside of prosthetic material 112 to provide stability and/or additional radial support. However, as in the main body component 120, it is contemplated that the stent 146 could also be placed on the inside of the prosthetic material 112, or the spiral stent 146 could be captured between two layers of prosthetic material (not shown). The prosthetic layer 112 could be a continuous tube or non-tubular. The prosthetic material 112 could cover the entire lumen extension 140 or the prosthetic material 112 could cover only a portion of the lumen extension. Furthermore, as previously discussed, the spiral stent 146 need not be one continuous stent along the length of the extension. The addition of the spiral stent 146 to the lumen extension 140 aids in the deployment of the lumen extension and allows for longitudinal compliance while maintaining radial support of the lumen within the lumen extension 140. Typically, radiopaque extension markers 148 are used on each end of the extension 140 to aid in the visualization of the placement of the lumen extension 140 within the lumen of the first distal opening 127 and the second distal opening 129 of the main body component 120.

As shown in Figs. 9A through 9D, the engaging stent or stents 150 in the lumen extension 140 can be sized, configured, and arranged to engage the stent rings 134 in the first lumen 126 and the second lumen 128 of the main body 120. The distal apices 147 of at least one engaging stent 150 are angled outwardly to engage the mating distal stent 134 on the main body component 120 (seen particularly in Figs. 9B and 9D). This engagement prevents the lumen extension 140 from moving or migrating axially in relation to the first lumen 126 and the second lumen 128 after the lumen extension 140 has been deployed. In an alternative embodiment shown in Figs. 10A through 10D, the spiral stents 146, which are attached to

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the outside of the lumen extension 140, may engage with the distal stents 134 of the main body 120 without being angled outwardly. In either of these embodiments, additional features may be included with the main body 120 or the lumen extensions 140 to help prevent the lumen extension 140 from moving or migrating axially in relation to the main body 120, such as hooks, barbs, loops of fabric or loops/folds of graft material, or pockets in graft material, for example.

During use (see Fig. 58), the deployment catheter 200 is navigated over the guide wire 30 through an iliac to the desired location within the aorta near the renal arteries. The catheter 200 carries the main body component 120 of the multi-lumen prosthesis system 100 in a radially reduced configuration. At the targeted site, the retaining jacket 210 is retracted which allows the distal stent 134 of the second lumen 128 to radially expand into the position shown in Fig. 60. The distal stent 134 of the first lumen 126 and the proximal stent 130 are not allowed to expand until releasing means have been activated.

As Figs. 69 and 70 show, the first lumen extension 140 is carried in a radially compressed condition by an over-the-wire extension catheter 350 coming from the contralateral iliac, for example. The catheter 350 deploys the first lumen extension 140, such that the proximal end 142 of the lumen extension 140 is telescopically received within the second lumen 128 of the main body component 120 and the distal end 144 extends into the contralateral iliac, as Fig. 71 shows. The second lumen extension 140 is then carried in a radially compressed condition by the extension catheter 350 coming from the ipsilateral iliac, for example. The extension catheter 350 deploys the second lumen extension 140, such that the proximal end 142 of the lumen

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extension 140 is telescopically received within the first lumen 126 of the main body component 120 and the distal end 144 extends into the ipsilateral iliac, as Fig. 77 shows. Only when each lumen extension 140 is
5 telescopically received within the first lumen 126 and second lumen 128 of the main body component 120, a bifurcated prosthesis 100 is formed with divergent lumens, as seen in Fig. 78.

IV. IMPLANTATION APPARATUS

10 A. Prosthesis Deployment Catheter

Fig. 11 shows a prosthesis deployment catheter 200 having features of the invention. The purpose of the catheter 200 is to (i) contain and/or restrain the main body prosthesis 120 prior to its deployment (see Fig. 14A), (ii) deliver the main body prosthesis 120 through
15 the vasculature to a desired location within the body, e.g., a hollow body organ or a blood vessel (see Fig. 1), and (iii) controllably deploy the main body prosthesis 120 in the desired location (see Figs. 2 and 3),
20 including maintaining a stable position of the main body prosthesis 120 in a partially deployed condition while the main body prosthesis is fastened to the vessel wall. In the illustrated embodiment, the proximal end 202 of the catheter 200 is shown positioned over a guide wire 30
25 in a body lumen (see Fig. 1). The catheter 200 carries the main body prosthesis 120 in a radially reduced configuration to the targeted site. At the targeted site, the catheter 200 releases the radially reduced prosthesis 120, which expands radially (see Figs. 2 and 3). After
30 partial or complete expansion or deployment of the main body prosthesis 120, one or more fasteners 402 are desirably introduced by a fastener device 400 to anchor the main body prosthesis 120 in place. The fasteners 402 may also serve to provide apposition of the prosthesis
35 material 112 to the hollow body organ or vessel wall and

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to seal and/or repair a fluid leak. Further details of the fastener device and fastener can be found in section three (3) below.

As previously described, the prosthesis 100 can be sized and configured to be either straight or bifurcated form. Fig. 4 depicts a completely deployed bifurcated prosthesis 100. Fig. 5 depicts a completely deployed straight prosthesis 50.

For the purposes of illustration, Fig. 1 shows the targeted site as being within an abdominal aortic aneurysm. Of course, the targeted site can be elsewhere in the body.

As shown in Figs. 11 through 14B, the catheter 200 comprises an inner assembly 208, an outer jacket 210, and a handle assembly 212. These components will now be individually described in greater detail.

1. The Inner Assembly

In the illustrated embodiment (see Figs. 12 through 14B), the inner assembly 208 comprises a central shaft 216, which functions as a carrier for the main body prosthesis 120, proximal and distal retaining means 218, 220, and a catheter tip component 222. The proximal retaining means 218 desirably comprises a first proximal retaining means 224 and a second proximal retaining means 226. The first proximal retaining means 224 desirably retains at least a portion of the main body prosthesis 120 in a radially compressed, and/or partially radially expanded condition prior to deployment and prior to fastening the main body prosthesis 120 to the vessel wall. The second proximal retaining means 226 desirably functions to stabilize the deployed proximal sealing stent 130 by preventing longitudinal and to a limited extent rotational movement. Each of the first and second proximal retaining means also desirably include a co-acting releasing means or mechanism 228, 230 for

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maintaining the first or second proximal retaining means 224, 226 in a desired relationship with the main body prosthesis 120 prior to activation. The distal retaining means or mechanism 220 also desirably includes a releasing means or mechanism 232 for activating/releasing the distal retaining means or mechanism 220. The releasing means may comprise a wide variety of devices, such as wire or wires, sutures, magnetics, or fluids, and may include sliding, pulling or pushing, for example.

10 a. The Central Shaft

In the embodiment shown in Figs. 13 and 14A, the central shaft 216 and the proximal and distal retaining means 218, 220 are located within the confines of the outer jacket 210. In this respect, the outer jacket 210 functions as an enclosure for the main body prosthesis 120 on the carrier (see Fig. 14A). In this arrangement, the catheter tip component 222 is attached to the proximal end of the central shaft 216, and the proximal end of the outer jacket 210 terminates adjacent the catheter tip component 222. Thus, the catheter tip component 222 extends outward beyond the outer jacket 210. The central shaft 216, the proximal and distal releasing means 228, 230, 232, and the outer jacket 210 may be coupled to the handle assembly 212 at the proximal end of the catheter handle assembly 212 (see Fig. 11). As can be seen in Fig. 14A, the main body prosthesis 120 is contained in a cavity 234 defined between the central shaft 216 and the outer jacket 210 in the proximal section of the deployment catheter 200.

30 The central shaft 216 extends from the handle assembly 212 to the catheter tip component 222. The central shaft 216 may be made, e.g., from stainless steel or other suitable medical materials including other metals or polymers. The central shaft 216 comprises at least one lumen, desirably more than one lumen, and more

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desirably four lumens.

One lumen may be described as the central lumen 236 (see Fig. 15), with an inner diameter between .010 and .120 inches, desirably between .020 and .060 inches and most desirably between .030 and .050 inches. As described, the central lumen 236 allows for the insertion of the guide wire 30 up to 0.038" diameter. The catheter tip component 222 also desirably has at least one lumen 238 (see Fig. 16) configured to align with at least one lumen within the central shaft 216. This lumen 238 allows for the insertion of the guide wire 30 through the central shaft 216 and through the catheter tip component 222. Typically this lumen 238 will have an inner diameter between .010 and .120 inches, desirably between .020 and .060 inches and most desirably between .030 and .050 inches.

b. Catheter Tip

Desirably, the catheter tip component 222 is flexible and has a long, tapered proximal end 240 and a shorter, tapered distal end 242. The maximum diameter of the catheter tip component 222 is approximately the same as the outside diameter of the proximal end of the outer jacket 210. The proximal end 240 of the catheter tip component 222 provides a smooth tapered transition from the lumen 238 containing the guide wire 30 to the proximal edge of the outer jacket 210. This feature aids in catheter insertion and navigation through tortuous anatomy over the guide wire 30. The tapered section on the distal end 242 of the catheter tip component 222 prevents the catheter tip component 222 from inadvertently engaging the main body prosthesis 120, portions of the surrounding anatomy, or an introducer sheath or the like during removal of the deployment catheter 200 from the body.

2. Proximal Retaining Means

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a. First Proximal Retaining Means

As can be seen in Figs. 17 through 19, in the illustrated embodiment, the first proximal retaining means 224 comprises at least one suture, or sutures, 252
5 and/or equivalent structures, which are coupled to the prosthetic material 112, or one or more stents 130 on the main body prosthesis 120. The suture 252 is, in turn, looped around the releasing means 228, e.g., a release wire 250, when the release wire 250 is in its proximal-
10 most position, as Figs. 17 and 18A shows. Distal retraction of the wire 250 withdraws the wire 250 from the suture loop 252, and allows the proximal end 108 of the main body prosthesis 120 to radially expand, as Fig. 19 shows. In an alternative embodiment, the suture 252
15 may comprise more than one suture, i.e., two or more suture loops. Fig. 18B shows the path of two suture loops 252 looped around the release wire 250.

Belt loops or the like may be provided on the main body prosthesis 120 and/or lumen extensions 140 to guide
20 and support the suture loop(s) along the path of the suture loop (see Figs. 17 and 46B for example). The belt loops can be spaced at desired circumferential intervals, such as every ninety degrees, for example.

In the illustrated embodiment, one end of the suture
25 loop 252 is coupled to the prosthetic material 112 or one or more stents 130 at or near the proximal end 108 of the main body prosthesis 120. The suture loop 252 is then looped around the main body prosthesis 120 and the releasing means 228 in a predetermined pattern, as shown
30 in Fig. 18A, in order to compress and retain the proximal end 108 of the prosthesis 120. The free end of the suture loop 252 is then coupled to the prosthetic material 112 or one or more stents 130 at or near the proximal end 108 of the main body prosthesis 120. Fig. 18B shows two
35 separate loops 252 looped around the main body prosthesis

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120 and the release wire 250. It should be appreciated, however, that suture loop 252 could be coupled to stents elsewhere in the main body prosthesis 120, and/or the other components of the main body prosthesis 120 as well.

5 The suture loop 252 and releasing means 228, e.g., release wire 250, of the embodiment just described retains the prosthesis 120 in a desired relationship to the central shaft (see Fig. 17). The suture loop 252 and the releasing means 228 help to keep the main body
10 prosthesis 120 from moving distally as the outer jacket 210 is retracted. The suture loop 252 also keeps the stent or stents 130 that are retained by the suture loop 252 in a radially compressed condition as the outer jacket 210 is retracted. The suture loop 252 and
15 releasing means 228 prevent the proximal end 108 of the main body prosthesis 120 from self-expanding until the releasing means 228 has been withdrawn. In the illustrated embodiment, the withdrawal of the releasing means 228 is accomplished by operating a control knob to
20 move the releasing means 228 distally, withdrawing the releasing means 228 away from the suture loop 252. Once the releasing means 228 is withdrawn, the restrained components of the main body prosthesis 120 are free to self expand, as Fig. 19 shows.

25 As can be seen in Figs. 20 and 21, the first proximal releasing means 228 comprises a first proximal release hub 244 positioned over the central shaft 216, and a release wire 250. The first proximal release hub 244 may include a small hole or lumen 246 in the proximal
30 end of the hub 244 that is in fluid communication with a first proximal release lumen 248 within the central shaft 216. Each lumen 246, 248 desirably includes a diameter sufficiently large to accommodate the first proximal release wire 250 extending from the handle assembly 212
35 to beyond the first proximal release hub 244. It is to be

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appreciated that the release wire 250 may extend external the shaft 216 as well.

The first proximal retaining means 224 holds the main body prosthesis 120 in a desired configuration prior to deployment (see Figs. 17 and 18A) and the first proximal releasing means 228 selectively releases the main body prosthesis 120 for the first stage of deployment (see Fig. 19). In the illustrated embodiment, the distal end of the first proximal release wire 250 is connected to an actuator or control button or knob in the handle assembly 212, as will be described further below.

The main body prosthesis 120 is retained by at least the first proximal retaining means 224 along the central shaft 216 in the cavity 234, which extends between the distal end 242 of the catheter tip component 222 and the proximal end of a spacer 206 (as best seen in Fig. 14A). In the illustrated embodiment, the releasing means 228 includes the release wire 250 that may extend through at least a portion of the central shaft 216. The proximal end of the wire 250 passes through the lumen 246 of the first proximal release hub 244. The first proximal release wire 250 is thereby kept in a desired relationship within or along the central shaft 216. The distal end of the first proximal release wire 250 is coupled to the control knob, such that fore and aft movement of the knob moves the release wire 250, respectively, proximally and distally.

As illustrated and described, the first proximal releasing means 228 is coupled to one restrained component of the main body prosthesis 120, i.e., suture loop 252. It should be appreciated, however, that the releasing means 228 can be coupled to the main body prosthesis 120 at two or more restrained regions, so that withdrawal of the releasing means 228 frees the prosthesis at two or more restrained regions. It should

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also be appreciated that the releasing means 228 can comprise more than a single releasing element. For example, multiple, individual releasing wires 250 could be coupled to the main body prosthesis 120 at different regions, so that release of separate regions of the main body prosthesis 120 can be individually controlled.

b. Second Proximal Retaining Means

Referring back to Fig. 12, the proximal retaining means 218 may also incorporate a second retaining means 226 which may function in cooperation with, or separate from the first proximal retaining means 224. The second proximal retaining means 226 may be held in place by the second proximal releasing means 230 in a predetermined, spaced relationship with the central shaft 216.

Referring now to Figs. 22 through 27, the second proximal retaining means 226 may comprise at least one stabilizing arm 256, and/or equivalent structures, and desirably more than one stabilizing arm, such as three stabilizing arms, as shown. The second proximal releasing means 226 may comprise a second proximal release hub 266 and a second proximal release wire or wires 268.

The distal ends 258 of the stabilizing arms 256 are coupled to the second proximal release hub 266. In a pre-deployment configuration, the proximal ends 262 of the stabilizing arms 256 are arched back generally toward the first proximal release hub 244 (see Figs. 23 and 24) and are releasably attached to the prosthesis material 112 at or near the proximal end 108 of the main body prosthesis 120 (see Figs. 24 and 25). In a post-deployment configuration, as seen in Fig. 26, the stabilizing arms 256 extend proximally toward the catheter tip 222.

The proximal ends 262 of the stabilizing arms 256 include a stabilizing arm aperture 264. In the pre-deployment configuration, the stabilizing arms 256 are positioned within the proximal opening 122 of the main

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body prosthesis 120 and the second proximal release wire 268 is stitched or otherwise extended through the stabilizing arm aperture 264 and through the prosthesis material 112, releasably securing the stabilizing arms 256 to the main body prosthesis 120 (as best seen in Fig. 25). Distal retraction of the second proximal release wire 268 (using a second control knob, to be described later) withdraws the second proximal release wire 268 from the prosthesis material 112 and releases the stabilizing arms 264. The main body prosthesis 120 is now free from the retentive feature of the stabilizing arms 256, and the stabilizing arms return to the post-deployment configuration, as shown in Fig. 26. It is to be appreciated that the second proximal release wire 268 may comprise multiple release wires, including one release wire for each stabilizing arm 256. The second proximal release wire 268 may comprise a single wire extending through the central shaft, and then divide into multiple wires to individually engage the stabilizing arms, or the release wire 268 may comprise multiple wires extending through the central shaft 216 to individually engage each stabilizing arm 256. In an alternative embodiment, the stabilizing arms 256 could be positioned in the reverse orientation on the catheter central shaft 216. Stabilizing arms of this configuration would be biased open away from the central shaft 216 and would require a secondary means to retain them in close proximity to the central shaft 216 in order to be rejaacketed before catheter removal.

In the embodiment shown in Figs. 24 through 27, the second proximal retaining means 226 includes a second proximal release hub 266 positioned over the central shaft 216. The second proximal release hub 266 may include a small hole or lumen 270 in the proximal end of the hub 266 that is in fluid communication with the

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second proximal release lumen 272 within the central shaft (see Figs. 24 and 27). The lumen 270 and 272 desirably includes a diameter sufficiently large to accommodate at least one second proximal release wire 268
5 extending from the handle portion 212 to beyond the second proximal release hub 266. It is to be appreciated that the release wire 268 may extend external the shaft 216 as well.

The second proximal retaining means 226 holds the
10 main body prosthesis 120 in a desired configuration prior to deployment (see Figs. 19 and 24) and selectively releases the main body prosthesis 120 for the second stage of deployment (see Fig. 26). In the illustrated embodiment, the distal end of the second proximal release
15 wire 268 is connected to an actuator or control button or knob in the handle assembly 212, as will be discussed further below.

The main body prosthesis 120 is retained by the second proximal retaining means 226 in a spaced apart
20 relationship to the central shaft 216 (see Fig. 24). In the illustrated embodiment, the second proximal releasing means 230 includes the second proximal release wire 268 that may extend through at least a portion of the central shaft 216. The proximal end of the release wire 268
25 passes through the lumen 270 of the second proximal release hub 266. The second proximal release wire 268 is thereby kept in a desired relationship within or along the central shaft 216. The distal end of the second proximal release wire 268 is coupled to the second
30 control knob, such that fore and aft movement of the second knob moves the second proximal release wire 268, respectively, proximally and distally.

3. Distal Retaining Means

As can be seen in Figs. 28 through 33, in the
35 illustrated embodiment, the distal retaining means 220

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comprises at least one suture, or sutures, 274 and/or equivalent structures, which are coupled to the prosthetic material 112, or one or more stents 134 on the main body prosthesis 120. Desirably, the suture 274 is
5 coupled to the prosthesis material 112 near the distal end 110 of the main body 120, and more desirably near the distal opening 127 of the first lumen 126. The suture 274 is, in turn, looped around the releasing means 232, e.g., a release wire 282, when the release wire 282 is in its
10 proximal-most position, as Figs. 28 and 29A show. Distal retraction of the wire 282 withdraws the wire 282 from the suture loop 274, and allows the distal end 110 of the main body prosthesis 120 to radially expand, as Fig. 30 shows. In an alternative embodiment, the suture 274 may
15 comprise more than one suture, i.e., two or more suture loops. Fig. 29B shows the path of two suture loops 252 looped around the release wire 292.

As described for the first proximal retaining means, belt loops or the like may be provided on the main body
20 prosthesis 120 and/or lumen extensions 140 to guide and support the suture loop(s) along the path of the suture loop. The belt loops can be spaced at desired circumferential intervals, such as every ninety degrees, for example.

25 In the illustrated embodiment, one end of the suture loop 274 is coupled to the prosthetic material 112 or one or more stents 134 at or near the distal end 110 of the main body prosthesis 120. The suture loop 274 is then looped around the main body prosthesis 120 and the distal
30 releasing means 232 in a predetermined pattern, as shown in Fig. 29A, in order to compress and retain the distal end 110 of the main body prosthesis 120. The free end of the suture loop 274 is then coupled to the prosthetic material 112 or one or more stents 134 at or near the
35 proximal end 110 of the main body prosthesis 120. Fig.

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29B shows two separate loops 252 looped around the main body prosthesis 120 and the release wire 250. It should be appreciated, however, that suture loop 274 could be coupled to stents elsewhere in the main body prosthesis 120, and/or the other components of the main body prosthesis 120 as well.

The suture loop 274 and releasing means 232, e.g., release wire 282, of the embodiment just described retain the distal end of the main body prosthesis 120 to the central shaft 216 (see Fig. 28). The suture loop 274 and the releasing means 232 keep the main body prosthesis 120 from moving distally as the outer jacket 210 is retracted. The releasing means 232 also keeps the stent or stents 134 that are retained by the suture loops 274 in a radially compressed condition as the outer jacket 210 is retracted. The suture loop 274 and releasing means 232 prevent the distal end 110 of the main body prosthesis 120 from self-expanding until the releasing means 232 has been withdrawn. In the illustrated embodiment, the withdrawal of the releasing means 232 is accomplished by operating a control knob to move the releasing means 232 distally, withdrawing the releasing means 232 and away from the suture loop 252. Once the releasing means 232 is withdrawn, the restrained components of the main body prosthesis 120 are free to self expand, as Fig. 30 shows.

In the embodiment shown in Figs. 28 through 31, the distal releasing means 232 includes a distal release hub 276 positioned over the central shaft 216 and a release wire 282. The distal release hub may include a small hole or lumen 278 in the proximal end of the hub that is in fluid communication with a distal release lumen 280 within the central shaft 216 (see Fig. 31). Each lumen 278, 280 desirably includes a diameter sufficiently large to accommodate a distal release wire 282 extending from

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the handle assembly 212 to beyond the distal release hub. It is to be appreciated that the release wire 282 may extend external to the shaft 216 as well.

5 The distal retaining means 220 holds the distal end 110 of the main body prosthesis 120 in a desired configuration prior to deployment of the distal end (see Fig. 28) and the distal releasing means 232 selectively releases the distal end 110 of the main body prosthesis 120 for the final stage of deployment (see Fig. 30). In
10 the illustrated embodiment, the distal end of the distal releasing means 232 is connected to an actuator or control button or knob in the handle assembly 212, as will be described further below.

In the illustrated embodiment, the distal releasing
15 means 232 includes the distal release wire 282 that may extend through at least a portion of the central shaft 216. The proximal end of the wire 282 passes through the lumen 278 of the distal release hub 276. The proximal end of the distal release wire 282 then may extend back into
20 the central shaft 216 through the second distal release hole or lumen 284 positioned spaced apart from the distal release hub 276. The proximal end of the release wire 282 is thereby kept in a desired relationship within or along the central shaft 216. The distal end of the distal
25 release wire 282 is coupled to the distal control knob, such that fore and aft movement of the distal control knob moves the distal release wire 282, respectively, distally and proximally.

As illustrated and described, the distal releasing
30 means 232 is coupled to the main body prosthesis 120 or a component of the main body prosthesis, i.e., suture loop 274. It should be appreciated, however, that the distal releasing means 232 can be coupled to the main body prosthesis 120 at two or more restrained regions, so that
35 withdrawal of the distal releasing means 232 frees the

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prosthesis at two or more restrained regions. It should also be appreciated that the distal releasing means 232 can comprise more than a single releasing element. For example, multiple, individual releasing wires 282 could
5 be coupled to the main body prosthesis 120 at different regions, so that release of separate regions of the distal end of the main body prosthesis 120 can be individually controlled.

In an alternative embodiment, the distal retaining
10 means 220 may comprise the prosthesis material 112. As can be seen in Fig. 32, the distal release wire 282 may be threaded through the prosthesis material 112 near the distal end 110 of the main body prosthesis 120, e.g., the first lumen 126. The distal release wire 282 then
15 desirably extends into the second distal lumen 284. The proximal end of the release wire 282 is thereby kept in a desired relationship within or along the central shaft 216 to retain the wire 282. In this configuration, the distal stent(s) 134 are not radially restrained. As the
20 outer jacket is retracted, the distal end 110 of the main body prosthesis 120 is free to radially expand. The distal release wire 282 serves to maintain the position of the distal end 110 relative to the catheter shaft 216. This feature allows for a greater flow of fluid through
25 the lumens of the main body prosthesis while still maintaining longitudinal or axial control of the main body prosthesis 120 during the deployment process. In the illustrated embodiment, the withdrawal of the release wire 282 is accomplished by operating a control knob to
30 move the release wire 282 distally, withdrawing the release wire 282 from the prosthesis material 112 and releasing the restrained components of the main body prosthesis 120 from the catheter shaft 216, as Fig. 33 shows.

35 B. The Outer Jacket

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As previously described, the outer jacket 210 serves to restrain the stents 130, 134 on the main body prosthesis 120 from expanding and allows for a controlled deployment of the main body prosthesis 120 within the body (see Fig. 14A). In the illustrated arrangement, the outer jacket 210 is coupled to an actuator or knob 302 on the handle assembly 212, as will be described in greater detail below.

As Fig. 14A shows, the outer jacket 210 extends proximally over the spacer 206 and main body prosthesis 120 and terminates adjacent the distal end 242 of the catheter tip component 222. Typically, the outer jacket 210 can be made of a polymer tube or similar materials known in the art. In one embodiment, the jacket 210 may be free of structural reinforcement. In an alternative embodiment (shown in Fig. 14B), the jacket 210 may include structural reinforcement, such as but not limited to, a wire or rod 211 positioned longitudinally along a length of the jacket, and/or a wire or rod 213 positioned helically around a length of the jacket. The structural reinforcement may also be in the form of a coil(s) or braided wire, for example. The plasticity of the structural reinforcement may be altered to affect the flexibility of the jacket 210 depending on a selected application. In addition, the structural reinforcement may extend along the full length of the jacket 210, or may be positioned along only a portion or portions of the length of the jacket. The structural reinforcement may be embedded within the jacket 210, or may be coupled to the interior or exterior surface of the jacket.

In the illustrated embodiment, the outer jacket 210 is configured to maintain a consistent diameter throughout its entire length (see Fig. 11). The outer jacket may also be tapered due to a difference in outer diameters of the catheter tip component 222. The diameter

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of the outer jacket 210 is intended to contain the main body prosthesis 120, and optionally an extension portion 140 or portions of the main body prosthesis 120, if present. The outer diameter continues distally to the handle assembly 212. The relatively small size of the outer diameter of the outer jacket 210 also allows for better blood circulation passed the deployment catheter 200.

Returning to Fig. 14A, the spacer 206 provides support for the outer jacket 210 and, by occupying space within the outer jacket 210, reduces the amount of air entrapped within the deployment catheter 200. The proximal end of the spacer 206 desirably terminates adjacent the distal end 110 of the main body prosthesis 120. In this arrangement, the cavity 234 containing the main body prosthesis 120 extends from the distal end 242 of the catheter tip component 222 to the proximal end of the spacer 206. As Fig. 14A shows, the spacer 206 is positioned over the central shaft 216 and the distal end of the spacer 206 is connected to the handle assembly 212. Typically, the spacer 206 can have an outer diameter slightly less than the inner diameter of the outer jacket 210. The spacer 206 can comprise a single lumen or an array of multiple lumens for passage of the various components within the spacer 206.

C. Handle Assembly

The handle assembly 212 provides the operator with longitudinal or axial control and rotational control of the deployment catheter 200 within the body and provides access to the actuator(s) or control means for deploying the main body prosthesis 120.

Referring to Figs. 34 through 36, the handle assembly 212 comprises a handle body 290, a jacket retraction means 292, which is connected to the distal end of the outer jacket 210, a sliding knob 294 which may

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also be connected to the distal end of the outer jacket 210, and at least one actuator or knob which is attached to the distal end of the proximal and distal releasing means. Desirably, the handle 212 comprises a separate
5 knob for each of the first proximal releasing means 228, the second proximal releasing means 230, and the distal releasing means 232.

In the illustrated embodiment, the central shaft 216 is captured within the handle 212 and has a guide wire
10 receiving luer 296 and an infusion valve 297 coupled to its distal end, which is located at the distal end of the handle assembly 212 (see Figs. 37 and 38). This feature prevents the position of the main body prosthesis 120 from moving relative to the handle body 212 while the
15 outer jacket 210 is retracted, and allows for irrigation or flushing of the catheter shaft 216, such as with a saline solution.

To withdraw the outer jacket 210 from the catheter tip 222 and expose the proximal end of the main body
20 prosthesis 120 (see Figs. 37 through 40), the jacket retraction means 292 is used. The jacket retraction means 292 may include a variety of different mechanisms to selectively control the retraction of the jacket 210 from the catheter tip 222. In the illustrated embodiment, the
25 jacket retraction means 292 comprises a rack and pinion type control mechanism to provide a mechanical advantage sufficient to withdraw the jacket 210 from the catheter tip 222. A pinion 298 is carried by a gear axle 300, and is rotated by a starting knob 302 positioned on at least
30 one end of the gear axle 300, as best seen in Fig. 41. A single starting knob may be present, or as shown in Figs. 39 and 40, two co-acting starting knobs 302 may be available for the clinician, one positioned on a first side 304 and one positioned on a second side 306 of the
35 handle 212. A complimentary rack 308 is carried by a

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jacket slide 310. The pinion 298 controls distal movement of the rack 308 along the jacket slide 310 between a first (jacket extended) position 312, shown in Fig. 39, and a second (jacket retracted) position 314, shown in
5 Fig. 40.

The jacket slide 310 is coupled to the jacket 210 and is temporarily coupled to the gear rack 308 via a spring loaded connecting pin 316. The connecting pin 316 disengages the jacket slide 310 at a predetermined
10 position in the handle body 290 by springing or otherwise retracting into a recess 318 in the handle body 290. When the connecting pin 316 disengages, the jacket slide 310 is free to travel in both a proximal and distal direction without re-engaging the rack 308. The rack 308 desirably
15 remains in this retracted position 314. A ratchet pawl, such as a spring backed ratchet pawl 320 may be coupled to the rack 308 to allow the rack to travel in a distal direction, but restrict proximal travel of the rack 308. Ratchet teeth 322 may be provided in the handle body 290
20 to engage the ratchet pawl 320.

Once the jacket slide 310 has traveled distally and the rack 308 has been disengaged, the jacket sliding knob 294 may then be used to continue the retraction of the jacket 210 from the main body prosthesis 120. The jacket
25 slide 310 is moved distally until the outer jacket 210 is free of the main body prosthesis 120 (see Fig. 60, for example). The portion or portions of the main body prosthesis 120 that are not coupled to the proximal and distal retaining means 218, 220, are free to self-expand,
30 as Fig. 60 shows. However, the portions of the main body prosthesis 120 that are coupled to the proximal and distal retaining means 218, 220, are still restrained from self-expansion, despite withdrawal of the outer jacket 210, as Fig. 60 also shows. The stent structure of
35 the main body prosthesis 120 is thereby kept restrained

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in a close relationship against the central shaft 216 while the outer jacket 210 is retracted. The proximal and distal retaining means 218, 220 prevents the main body prosthesis 120 from moving relative to the central shaft 216 during retraction of the outer jacket 210, which potentially minimizes blood flow through the main body prosthesis 120 during the deployment process. Furthermore, as described, the main body prosthesis 120 is not "pushed out" of the catheter. The main body prosthesis 120 therefore need not have longitudinal stiffness or a stent structure with a "spine".

To employ the first proximal retaining means 224, the first proximal sliding knob 322 (see Fig. 34) is moved distally until the proximal end of the first proximal releasing means 228 is withdrawn from the first proximal retaining means 224, as previously described. In the illustrated embodiment, the first proximal release wire 250 is positioned within the loops of the suture loop 252, as seen in Figs. 17 and 18A. As the first proximal release wire 250 is withdrawn from the suture loop 252, the suture loop 252 releases its retentive feature, yet may remain coupled to the prosthesis material 112. The proximal end 108 of the main body prosthesis 120 is thereby free to self-expand to its first stage deployment configuration, as Fig. 19 shows.

The same process is repeated for the second proximal retaining means 226 and the distal retaining means 220. To employ the second proximal retaining means 226, the second proximal sliding knob 324 (see Fig. 35) is moved distally until the proximal end of the second proximal releasing means 230 is withdrawn from the second proximal retaining means 226, as previously described. The proximal end 108 of the main body prosthesis 120 is thereby finally released from the catheter shaft 216, as Fig. 26 shows. To employ the distal retaining means 220,

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the distal sliding knob 326 (see Fig. 35) is moved distally until the proximal end of the distal releasing means 232 is withdrawn from the distal retaining means 220. The distal end 110 of the main body prosthesis 120 is thereby free to self-expand to its final deployment configuration, as Fig. 30 shows. Each of these steps will be described in greater detail in section V. It is to be appreciated that the sliding buttons or knobs may all be positioned on the first side 304 of the handle, or all may be positioned on the second side 306 of the handle, or may be positioned with one or more on the first side 304 and one or more on the second side 306, as shown. It should also be appreciated that the knobs 322, 324, 326, can comprise separate components that are not part of the handle assembly 212, i.e., on the outer jacket 210.

The proximal and distal retaining means 218, 220, desirably cooperate with a release system 328 positioned within the handle housing 290 (see Figs. 37 and 38). Each sliding knob 322, 324, 326, is coupled to a release slide 330, 332, 334, respectively, positioned within a track 336, 338, 340, respectively, in or on the release system 328 (see Figs. 41 through 43). Each release slide is coupled to the distal end of the releasing means, such as a release wire. It is to be appreciated that the release system 328 may also include an interlock system, such as a mechanical linkage for controlling the order by which the slides may be moved. In addition, an interlock system could also include a mechanical linkage to the jacket retraction slide 310. This feature would prevent the activation of the release slides until the jacket had been retracted to a predetermined position. It is also to be appreciated that the sliding knobs may include a symbol to indicate to the clinician an appropriate order of deployment.

As described, the main body prosthesis 120 is not

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released immediately from proximal end to distal end as the jacket 210 is withdrawn. The proximal and distal stent or stents 130, 134, are released in a secondary operation, which follows the withdrawal of the outer jacket 210. Placement of the prosthesis extensions 140 can therefore comprise a next step in the deployment process.

1. Lumen Extension Deployment Catheter

After the main body of the prosthesis 120 has been partially or completely deployed, a lumen extension 140, or lumen extensions, are next to be implanted. An extension deployment catheter 350 is shown in Fig. 44. It is to be appreciated that the extension deployment catheter 350 may incorporate all the features disclosed in the description of the deployment catheter 200. The extension catheter is used for delivery and deployment of the lumen extensions 140 to the targeted site.

In the illustrated embodiment, the extension catheter 350 carries the lumen extension 140 in a radially reduced configuration to the targeted site. At the targeted site, the extension catheter 350 releases the radially reduced lumen extension 140, which expands radially, and is coupled to a lumen of the main body prosthesis 120, as will be described further in section V.

As shown in Figs. 44 through 45B, the extension catheter 350 comprises an inner assembly 358, an outer jacket 360, and a handle assembly 362. These components will now be individually described in greater detail.

30 a. The Inner Assembly

In the illustrated embodiment (see Fig. 45A), the inner assembly 358 comprises a central shaft 364, which functions as a carrier for the lumen extension 140, proximal retaining means 366, and an extension catheter tip component 368. The proximal retaining means 366

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desirably retains at least a portion of the lumen extension 140 in a radially compressed or partially radially expanded condition prior to deployment and prior to coupling to the main body prosthesis 120. The proximal retaining means 366 also desirably includes a co-acting releasing means or mechanism 370 for maintaining the proximal retaining means 366 in a desired relationship with the lumen extension 140 prior to activation.

In an alternative embodiment (see Fig. 45B), the inner assembly may also include distal retaining means 367. The distal retaining means 367 desirably retains at least the distal portion of the lumen extension 140 in a radially compressed or partially radially expanded condition prior to deployment and prior to coupling to the main body prosthesis 120. The distal retaining means 367 also desirably includes a co-acting releasing means or mechanism 371 for maintaining the distal retaining means 367 in a desired relationship with the lumen extension 140 prior to activation.

b. The Central Shaft

In the embodiments shown in Fig. 45A and 45B, the central shaft 364 and the proximal and distal retaining means 366, 367 are located within the confines of the outer jacket 360. In this respect, the outer jacket 360 functions as an enclosure or jacket for the lumen extension 140 on the shaft 364 (see Figs. 46A and B). In this arrangement, the catheter tip component 368 is attached to the proximal end of the central shaft 364, and the proximal end of the outer jacket 360 terminates adjacent the catheter tip component 368. Thus, the extension catheter tip component 368 extends outward beyond the outer jacket 360. The central shaft 364, the proximal releasing means 366, the distal releasing means 367 (shown in Fig. 45B), and the outer jacket 360 are coupled to the handle assembly 362 at the proximal end of

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the catheter handle assembly 362 (see Fig. 44). As can be seen in Fig. 46A and 46B, the lumen extension 140 is contained in a cavity 372 defined between the central shaft 364 and the outer jacket 360 in the proximal
5 section of the extension catheter 350.

The central shaft 364 extends from the handle assembly 362 to the catheter tip component 368. The central shaft 364 may be made, e.g., from stainless steel or other suitable medical materials including other
10 metals or polymers. The central shaft 364 comprises at least one lumen, and may comprise more than one lumen.

One lumen may be described as the central lumen 374 (see Fig. 47A and 47B), with an inner diameter between .010 and .120 inches, desirably between .020 and .060
15 inches and most desirably between .030 and .050 inches. As described, the central lumen 374 allows for the insertion of a guide wire, i.e., the first guide wire 30 or the second guide wire 40, up to 0.038" diameter, for example. The catheter tip component 368, having the same
20 features as described for the catheter tip 222 of the deployment catheter 200, also desirably has at least one lumen 376 (see Fig. 45A) configured to align with at least one lumen within the central shaft 364. This lumen 376 allows for the insertion of the guide wire through
25 the central shaft 364 and through the extension catheter tip component 368. Typically this lumen 376 will have an inner diameter between .010 and .120 inches, desirably between .020 and .060 inches and most desirably between .030 and .050 inches.

30 c. Proximal Retaining Means

The proximal retaining means 366 and the proximal releasing means 370 may function in the same or similar fashion as the retaining means 224, 226, and the releasing means 228, 230 embodied in the deployment
35 catheter 200, as previously shown and described. As can

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be seen in Figs. 46A and 48A, in the illustrated embodiment, the proximal retaining means 366 comprises at least one suture, or sutures, 378 and/or equivalent structures, which are coupled to the lumen extension
5 prosthetic material 112, or to one or more stents 150 on the lumen extension 140. The suture 378 is, in turn, looped around the proximal releasing means 370, e.g., a release wire 380, when the release wire 380 is in its proximal-most position, as Figs. 46A and 48A show. Distal
10 retraction of the wire 380 positioned within a releasing wire lumen 381 (see Figs. 45A and 47A) withdraws the wire 380 from the suture loop 378, and allows the proximal end 142 of the lumen extension 140 to radially expand, as can be seen in Figs. 70 and 71. In an alternative embodiment,
15 the suture 378 may comprise more than one suture, i.e., two or more suture loops. Fig. 48C shows the path of two suture loops 378 looped around the release wire 380.

As described for the main body prosthesis 120, belt loops or the like may be provided on the lumen extensions
20 140 as well to guide and support the suture loop(s) along the path of the suture loop. The belt loops can be spaced at desired circumferential intervals, such as every ninety degrees, for example.

As can be seen in Fig. 45A, the proximal releasing
25 means 370 comprises a proximal release hub 397 positioned over the central shaft 364, and the release wire 380. The proximal release hub 397 may include a small hole or lumen 398 in the proximal end of the hub 397 that is in fluid communication with the proximal releasing wire
30 lumen 381 within the central shaft 364. Each lumen 381, 398 desirably include a diameter sufficiently large to accommodate the release wire 380 extending from the handle assembly 362 to beyond the release hub 397. It is to be appreciated that the release wire 380 may extend
35 external the shaft 364 as well.

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d. Distal Retaining Means

In an alternative embodiment, the distal retaining means 367 and the distal releasing means 371 may function in the same or similar fashion as the retaining means 220, and the releasing means 232 embodied in the deployment catheter 200, as previously shown and described. As can be seen in Figs. 46B and 48B, the distal retaining means 367 comprises at least one suture, or sutures, 379 and/or equivalent structures, which are coupled to the lumen extension prosthetic material 112, or to one or more stents 150 on the lumen extension 140. The suture 379 is, in turn, looped around the distal releasing means 371, e.g., a release wire 383, when the release wire 383 is in its proximal-most position, as Figs. 46B and 48B show. Distal retraction of the wire 383 positioned within a releasing wire lumen 385 (see Figs. 45B 47B) withdraws the wire 383 from the suture loop 379, and allows the distal end 144 of the lumen extension 140 to radially expand. As described for the proximal retaining means 366, the suture 379 may also comprise more than one suture, i.e., two or more suture loops. Fig. 48C shows the path of two suture loops 378 looped around the release wire 380. This path may also be used for suture loops 379 looped around the release wire 383.

As can be seen in Fig. 45B, the distal releasing means 371 comprises a distal release hub 399 positioned over the central shaft 364, and the release wire 383. The distal release hub 399 may include a small hole or lumen 395 in the proximal end of the hub 399 that is in fluid communication with the distal releasing wire lumen 385 within the central shaft 364. Each lumen 385, 395 desirably include a diameter sufficiently large to accommodate the release wire 383 extending from the handle assembly 362 to beyond the release hub 399. It is to be appreciated that the release wire 383 may extend

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external the shaft 364 as well.

B. The Outer Jacket

The outer jacket 360 may function in the same or similar fashion as described for the outer jacket 210 embodied in the deployment catheter 200. The outer jacket 360 also serves to restrain the stents 146 and 150 on the lumen extension 140 from expanding and allows for a controlled deployment of the lumen extension 140 within a lumen of the main body prosthesis 120. In the illustrated arrangement, the outer jacket 360 is coupled to an actuator or knob 382 on the handle assembly 362, as will be described in greater detail below.

As Figs. 46A and 46B show, the outer jacket 360 extends proximally over a spacer 384 and lumen extension 140 and terminates adjacent the distal end of the catheter tip component 368. Typically, the outer jacket 360 can be made of a polymer tube or similar materials known in the art. In one embodiment, the jacket 360 may be free of structural reinforcement. In an alternative embodiment (shown in Fig. 46C), the jacket 360 may include structural reinforcement, such as but not limited to, a wire or rod 361 positioned longitudinally along a length of the jacket, and/or a wire or rod 363 positioned helically around a length of the jacket. The structural reinforcement may also be in the form of a coil(s) or braided wire, for example. The plasticity of the structural reinforcement may be altered to affect the flexibility of the jacket 360 depending on a selected application. In addition, the structural reinforcement may extend along the full length of the jacket 360, or may be positioned along only a portion or portions of the length of the jacket. The structural reinforcement may be embedded within the jacket 360, or may be coupled to the interior or exterior surface of the jacket.

If desired, and as shown in Fig. 44B, a stationary

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outer jacket 365 may be provided that extends from the proximal end of the handle assembly 362. The jacket 360 slides within the stationary jacket 365. The stationary jacket 365 provides a seal interface with a hemostatic valve at the access site. The stationary jacket 365 can be made of a suitable medical grade plastic, such as Fluorinated Ethylene Propylene (FEP) as non-limiting example. The stationary outer jacket 365 provides column strength and lubricity to reduce friction during sliding actuation of the jacket 360. The stationary outer jacket 365 may also be provided for the prosthesis deployment catheter 200 for the same purposes.

C. Handle Assembly

The handle assembly 362 may function in the same or similar fashion as described for the handle assembly 212 embodied in the deployment catheter 200. The handle assembly 362 provides the operator with longitudinal or axial control and rotational control of the extension deployment catheter 350 within the body and provides access to the actuator(s) or control means for deploying the lumen extension 140.

Referring to Figs. 49 and 50, the handle assembly 362 comprises a handle body 386, a jacket retraction means 382, which is connected to the distal end of the outer jacket 360, and at least one knob or button 392 which is attached to the distal end of the proximal releasing means 370. It is to be appreciated that the handle assembly 362 may also include at least one knob or button 393 (see Fig. 49B) attached to an optional distal releasing means 371 and the knob or button may function in the same or similar fashion as described below for the proximal releasing means 370.

In the illustrated embodiment, the central shaft 364 is captured within the handle 362 and has a guide wire receiving luer 388 and an infusion valve 390 coupled to

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its distal end, which is located at the distal end of the handle assembly 362 (see Figs. 50 and 51). This feature prevents the position of the lumen extension 140 from moving relative to the handle body 362 while the outer jacket 360 is retracted, and allows for irrigation or flushing of the catheter shaft 364, such as with a saline solution.

To withdraw the outer jacket 360 from the catheter tip 368 and expose the lumen extension 140, jacket retraction means, such as the jacket retraction knob 382 may be used. The jacket retraction means 382 may include a variety of different mechanisms to selectively control the retraction of the jacket 360 from the catheter tip 368. In the illustrated embodiment, the jacket retraction means comprises two co-acting retraction knobs 382 which are available for the clinician, one positioned on each side of the handle 362.

The jacket retraction knob 382 is used to retract the jacket 360 from the lumen extension 140. The jacket retraction knob 382 is moved distally until the outer jacket 360 is free of the lumen extension 140 (see Fig. 70). The portion or portions of the lumen extension 140 that are not coupled to the proximal retaining means 366 are free to self-expand, as Fig. 70 shows. However, the portions of the lumen extension 140 that are coupled to the proximal retaining means 366 are still restrained from self-expansion, despite withdrawal of the outer jacket 360. The stent structure of the lumen extension 140 is thereby kept restrained in a close relationship against the central shaft 364 while the outer jacket 360 is retracted. The proximal retaining means 366 prevents the lumen extension 140 from moving relative to the central shaft 364 during retraction of the outer jacket 360, which potentially minimizes blood flow through the lumen extension 140 during the deployment process.

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Furthermore, as described, the lumen extension 140 is not "pushed out" of the extension catheter 350. The lumen extension 140 therefore need not have longitudinal stiffness or a stent structure with a "spine".

5 To employ the proximal retaining means 366, the proximal release sliding knob 392 (see Figs. 49A and 50) is moved distally until the proximal end of the proximal releasing means 370 is withdrawn from the proximal retaining means 366, as previously described. In the
10 illustrated embodiment, the proximal release wire 380 is positioned within the loops of the suture loop 378, as seen in Figs. 46A and 48A. As the proximal release wire 380 is withdrawn from the suture loop 378, the suture loop 378 releases its retentive feature, yet may remain
15 coupled to the prosthesis material 112. The proximal end 142 of the lumen extension 140 is thereby free to self-expand to its deployment configuration and couple itself within the lumen of the main body prosthesis 120, as Figs. 70 and 71 show. The natural flow of fluid through
20 the new extension 140 provides sufficient force to cause the restraint mechanism of the lumen extension 140 to engage the co-acting restraint mechanism of the main body prosthesis 120. The lumen extension stent and/or the outwardly extending apices 147 of the lumen extension
25 stent 150 engage the mating outwardly extending apices 136 of the main body prosthesis stent 134 (see Fig. 10B). Each of these steps will be described in greater detail in section V. It is to be appreciated that the sliding buttons or knobs may all be positioned on one side of the
30 handle, or all may be positioned on the opposite side of the handle, or may be positioned on both sides, as shown. It should also be appreciated that the knobs 382 and 392 can comprise separate components that are not part of the handle assembly 362, i.e., on the outer jacket 360.

35 The proximal retaining means 366 desirably cooperate

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with a release system 394 positioned within the handle housing 386. Proximal release sliding knob 392 is coupled to a release slide 396 positioned within a track 398 in or on the release system 394 (see Fig. 51). The release
5 slide 396 is coupled to the distal end of the releasing means 370, such as the release wire 380. It is to be appreciated that the release system 394 may also include an interlock system, such as a mechanical linkage for controlling the order by which the slides may be moved.
10 In addition, an interlock system could also include a mechanical linkage to the jacket retraction slide 382. This feature would prevent the activation of the release slides until the jacket had been retracted to a predetermined position. It is also to be appreciated that
15 the sliding knobs may include a symbol to indicate to the clinician an appropriate order of deployment.

As described, the lumen extension 140 is not released immediately from proximal end to distal end as the jacket 360 is withdrawn. The lumen extension stent or
20 stents 146 and 150 may be released in a secondary operation, which follows the withdrawal of the outer jacket 360. Placement of the prosthesis extensions 140 can therefore comprise a final step in the deployment process.

25 D. Fastener Device And Fastener

As previously described, one or more fasteners 402 (see Fig. 52) may be introduced by a fastener device 400 to anchor the prosthesis 100 in place. Typically the fasteners 402 will be introduced at the proximal end of
30 the main body prosthesis 120; however, it should be appreciated that the fasteners can be introduced in any part of the prosthesis 100, including the lumen extensions 140, to anchor it in place. In addition, the fasteners 402 may also serve to provide apposition of the
35 prosthesis material 112 to the hollow body organ or

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vessel wall. Fasteners may also be used to seal and/or repair leaks or seepage of fluid (e.g., around the proximal stents and/or distal stents of the prosthesis 100). One or more fasteners 402 may be introduced into the prosthesis 100 at different times or at the same time during the procedure.

As can be seen in Figs. 53 and 54, the fastener tool 400 desirably comprises a handle assembly 404 including a control assembly 406 and an indication assembly 408. A fastener delivery shaft 409, having a fastener driver 411 at its proximal end 410, is coupled to the proximal end of the handle assembly 404 for delivery of the fastener 402. Coupled to the distal end of the handle assembly may be an irrigation port or infusion valve 422.

The handle assembly 404 provides the fastening control feature for the clinician. Positioned within the handle assembly 404 is the control assembly 406. The control assembly provides motion control, such as a forward and reverse drive feature, for turning or otherwise moving the fastener 402 to or from a fastening position. The control assembly desirably includes a forward control button 412 and a reverse control button 414. The forward and reverse control buttons 412, 414 provide the clinician an ergonomic and single finger control of the fastener device 400.

The handle assembly desirably includes an indication assembly 408 to provide control information to the clinician. The indication assembly may include indication lights, i.e., LEDs, and/or the ability to produce audible signals (tones) to provide visual and/or audible indication of forward or reverse movement of the fastener 402, for example, by way of a variety of tones and/or a forward light 416 and a reverse light 418. Additionally, the indication assembly may include status tones and/or a status light 420 to provide a variety of information back

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to the clinician. The tones may use a variety of pitches or pulses, for example, and the status light 420 may use a variety a flash signals and illumination times; for example, to provide these different indications for the
5 clinician, such as error indication, position indication, and timing indication, for example.

Further details of the fastener device 400 and fastener 402 can be found in United States Patent Application Serial No. 10/307,226, filed November 29,
10 2002, and entitled "Intraluminal Prosthesis Attachment Systems and Methods," and in U.S. Patent Application Serial No. 10/786,465, filed February 29, 2004 and entitled "Systems and Methods for Attaching a Prosthesis Within a Body Lumen or Hollow Organ," which are both
15 incorporated herein by reference.

In this embodiment, the proximal coil 422 of the fastener 402 is formed to produce a diagonal member 424, which crosses the diameter of the helical fastener. The distal end of the fastener 402 comprises a sharpened tip
20 426, such as a conical tip or a chiseled tip, for example, to aid in the ease of tissue penetration. Similar helical fasteners are described in U.S. Patent No. 5,964,772; 5,824,008; 5,582,616; and 6,296,656, the full disclosures of which are incorporated herein by
25 reference.

In an alternative embodiment, the fastener device 400 and a fastener 430 may comprise features allowing the fastener 430 to be releasably secured to the fastener driver 432. As can be seen in Figs. 79A and 79B, the proximal coil 434 of the helical fastener 430 desirably
30 includes a diagonal member 436, which crosses the diameter of the fastener 430. The diagonal member 436 may bisect the diameter of the fastener 430, or may be offset, forming a "D" shaped proximal coil 434, as shown.
35 The diagonal member 436 desirably comes completely across

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the diameter to prevent the fastener 430 from being an open coil and to control the depth of penetration into the tissue. In addition, the diagonal member 436 can be attached to a previous coil, as shown, to strengthen the entire structure and provide a retentive shape for a fastener driver 432. This attachment could be achieved via welding, adhesive or any other suitable means.

Located at the proximal end of the fastener delivery shaft 410 is the fastener driver 432. In the illustrated embodiment (see Figs. 80 and 81), the fastener driver 432 includes a fastener carrier 438 positioned within a threaded fastener housing 439. The threaded fastener housing 439 may include tabs 437 or other coupling means so as to snap fit or couple to the fastener carrier 438 for convenient replacement. The coupling between the driver 432 and carrier 438 can take different forms - e.g., magnets, graspers, or other suitable mechanical connection. In the embodiment illustrated in Figs. 80 and 81, the driver 432 and carrier 438 are integrally connected as a single unit.

The carrier 438 is sized and configured to engage a selected fastener 430. The diagonal member 436 serves to define a shape, such as a "D" shape, to engage the carrier 438, which rotates the fastener 430 positioned over the carrier 438 to achieve fastening the prosthesis to tissue. The diagonal member 436 also serves as a stop to prevent the helical fastener 430 from penetrating too far into the tissue.

As can be seen in Figs. 80 and 81, a fastener 430 is positioned within the fastener housing 439 and over the carrier 438. The carrier 438 includes a release latch 440. The release latch 440 may be spring loaded, magnetic, or lever action, for example. The latch 440 prevents the premature release of the fastener 430. The release latch 440 desirably requires a force to overcome

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the securing force of the latch. For example, the release latch 440 may be overcome by a pulling force, e.g., the fastener 430 is being fastened through the prosthesis and within tissue and the pulling force of the fastener turning or screwing into tissue may overcome the securing force of the release latch. Alternatively, the release latch 440 may be overcome by a magnetic force activated by the clinician by pressing a release button 444 on the handle assembly 404 (shown in Fig. 86). In one embodiment shown in Figs. 82A and 82B, the release latch 440 includes a lever arm 442 to provide the latching force. As the carrier 438 is rotated to deploy the fastener 430, the force of the fastener 430 rotating into the tissue may be adequate to overcome the force of the release latch 440. As seen in Fig. 82A, the fastener 430 remains fastened to the carrier 438 by way of the fastener release latch 440. As seen in Fig. 82B, further rotation of the fastener 430 into tissue will cause each coil of the fastener to overcome the force of the release latch 440 and allow the fastener 430 to exit off of the carrier 438.

In an alternative embodiment, the release latch 440 may include a release spring 445, as seen in Fig. 82C. The release spring 445 is sized and configured to provide a sufficient force to maintain the fastener 430 on the carrier 438, and yet allow the fastener 430 to overcome the force of the release spring 445 and release latch 440 as the fastener is being screwed into tissue.

The fastener housing 439 desirably includes a predetermined amount of internal threads 441 (e.g., two or three threads). In this configuration, the threaded portion of the housing 439 may not be continuous throughout the length of the housing. The threads 441 engage the fastener 430 when the fastener is being loaded onto the fastener driver 432 (as described below) and

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also partially drive the helical fastener 430 out of the fastener driver 432 and into tissue. Desirably, the threaded portion of the threaded housing terminates a predetermined distance from the housing tip 443. This
5 unthreaded portion of the threaded housing 439 provides an area in which the fastener 430 can be rotated but not be driven out of the fastener driver 432. This unthreaded feature of the housing 439 allows the fastener 430 to pull itself out of the fastener driver 432 when rotated
10 by the driver only as long as the fastener 430 has been previously engaged with the prosthesis 120 and tissue. This feature ensures a more uniform depth of penetration for the fastener 430.

A helical fastener, such as 402 and 430, for
15 example, may be positioned in a fastener cassette 446, as seen in Figs. 83 and 84. The fastener cassette 446 may take on any convenient shape, such as a rectangle or circle, as shown, and may include any convenient number of fastener receptacles 448, such as six, although any
20 number may be used. The cassette 446 may be used to store and retain fasteners during shipment, and also to provide a convenient means to present the fastener 430, for example, to the fastener device 400 during a medical procedure.

25 As seen in Figs. 83 and 84, the fastener receptacle 448 is sized and configured to allow the proximal end 410 and the fastener driver 432 of the fastener device 400 access to the seated fastener 430. The fastener 430 may be positioned on a receptacle post 449, to hold the
30 fastener 430 within the receptacle 448. Or alternately, the fastener 430 may be held within the receptacle 448 through interference between the fastener 430 and the receptacle 448, or by penetrating the fastener tip 426 into a material at the base of the receptacle 448. The
35 receptacle post 449 may include a receptacle post spring

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447, allowing the receptacle post 449 to retreat into the receptacle 448 as the fastener driver 432 is inserted into the receptacle 448 to position the fastener 430 on to the carrier 438.

5 Figs. 85 and 86 show an embodiment of a fastener 430 being positioned within the fastener driver 432. As can be seen the fastener driver 432 is positioned on top of the receptacle 448 and gently inserted into the receptacle. The force of the insertion allows the
10 fastener 430 to overcome the force of the release latch 440 on the carrier 438 and to be positioned over the carrier 438. The fastener driver is then reversed, using the control assembly 406 provided on the fastener driver handle 404. The internal threads 441 of the threaded
15 housing 439 draw the fastener 430 into the fastener driver 432 and into position for deployment. Fig. 86 shows the fastener 430 removed from the cassette 446 and positioned on the fastener driver 432. It is to be appreciated that the cassette 446 can be used to hold a
20 variety of fastener shapes and sizes, and is not limited to the fastener 430, as described.

E. Steerable Guide Device

A steerable guide device 450 may be used to establish an open path through which an operative tool,
25 such as the fastener device 400, can be deployed for use. Figs. 55 and 56 show an embodiment of the steerable guide device 450. The steerable guide device comprises a flexible guide tube 452 carried by a handle 454. The handle is sized and configured to be ergonomically held
30 by the clinician to introduce the guide tube 452 to the targeted site.

In order to establish an open path for the fastener device 400, the steerable guide device 450 includes an interior guide passage 456 which extends through the
35 interior portion of the handle 454 continuously and into

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and through the guide tube 452. The distal end of the handle 454 may also include a seal 457 to restrict the flow of fluids through the guide tube 452. During introduction of the guide tube through the vasculature to the targeted site, an obturator or dilator 458 having a tip component 459 (see Fig. 57) is positioned within the guide tube 452 in order to seal the guide tube and restrict the flow of fluids through the guide tube 452, to provide an atraumatic tip for guiding through the vasculature, and to provide a guide wire lumen 470.

The handle assembly desirably includes a rotatable steering assembly 460 and a flushing port 462. The steering assembly 460 is used to deflect the proximal end 464 of the guide tube 452 to a bent or deflected configuration, as will be described later. The steering assembly 460 is rotated in a desired direction, causing the proximal end 464 to bend or deflect in a predetermined configuration. A radiopaque marker 466 can be placed on the proximal end region 464 of the guide tube 452 to allow for fluoroscopic visualization of the orientation of the deflected end region. In the bent or deflected configuration, the proximal end 464 can be oriented in a desired relationship with the targeted site.

Further details of the steerable guide device 450 can be found in United States Patent Application Serial No. No. --/-----, (to be supplied), filed 20 October 2005, and entitled "Devices, Systems, and Methods for Guiding an Operative Tool Into an Interior Body Region," which is incorporated herein by reference.

V. DETAILED IMPLANTATION METHODS

The generally described steps of implantation of the prosthesis 100 provided in Section II will now be described in greater detail. In the illustrated embodiment, deployment of the bifurcated prosthesis 100

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may generally be achieved in a twelve step process, for example, and is shown generally in Figs. 58 through 78. The exemplary embodiment will describe the systems, methods, and uses of the tools for implanting the
5 prosthesis 100. It is to be understood that these same or similar systems, methods, and tools may be used to implant other prosthesis configurations in other areas of the body as well. Throughout the implantation process, image guidance may be used and in conjunction with
10 radiopaque markers positioned on the prosthesis 100 and deployment tools.

Access to the vascular system is commonly provided through the use of introducers known in the art. A hemostasis introducer sheath (not shown), for example,
15 may be first positioned in the left femoral artery, providing access for the implantation tools. A second introducer sheath (not shown) may also be positioned in the right femoral artery, providing access for the implantation tools. It is to be understood that
20 alternative access points may also be used. Access at both the left femoral artery and the right femoral artery, for example, allows for multiple implantation tools to be positioned within the vasculature at the same time, allowing the implantation procedure to be
25 efficiently performed.

A. Position Main Body Prosthesis

A first step includes positioning the main body prosthesis 120 at the desired location. From either the left or right femoral artery, under image guidance, the
30 first guide wire 30 is advanced into the ipsilateral iliac artery and to the descending aorta. The deployment catheter 200 is then navigated over the first guide wire 30 to the desired location within the body, (e.g., aortic aneurysm), for deployment of the main body prosthesis 120
35 (as Fig. 58 shows). A conventional hemostatic valve

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arrangement may be used at the access site (shown for purposes of illustration in Fig. 44B).

B. Retract Outer Jacket

Next, the outer jacket 210 is retracted in a distal
5 or caudal direction to expose the main body prosthesis 120. By first rotating the starting knob 302 on the handle assembly 212, the outer jacket 210 is initially retracted from its secure position on the catheter tip 222. After the mechanical advantage provided by the
10 rotation of the starting knob 302 has retracted the outer jacket 210 away from the catheter tip 222, the jacket sliding knob 294 on the handle 212 may be used to further retract the jacket 210 and fully expose the main body prosthesis 120 (as Figs. 59 and 60 show). The
15 unrestrained portion or portions of the main body prosthesis 120 self-expand, as can be seen in Fig. 60. Optionally, the first lumen 126 may not be radially restrained, but still restrained in relation to the central shaft 216 (see Fig. 32), so as the outer jacket
20 210 is retracted, the first lumen 126 may self expand as well, as can be seen in Fig. 61. As Figs. 59 through 61 show, both during and after retraction of the outer jacket 210, the main body prosthesis 120 maintains its position relative to the central shaft 216 due to the
25 proximal and distal retaining means 218, 220, coupled to the main body prosthesis 120.

It should be appreciated that the withdrawal of the outer jacket 210 and the withdrawal of the proximal and distal releasing means 228, 230, 232, or any combination
30 thereof, can be accomplished in a single step or process or in multiple steps. In this arrangement, a single activation mechanism can be jointly coupled to the outer jacket 210 and any or all of the releasing means 228, 230, 232, so that the outer jacket 210 and releasing
35 means 228, 230, 232, are withdrawn in a single step, or

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multiple steps.

C. Release First Proximal Retaining Means

In the third general step of the deployment process, following the withdrawal of the outer jacket 210, the first proximal sliding knob 322 on the handle assembly 212 is moved distally, which causes the proximal end of the first proximal releasing means 228, i.e., the first proximal release wire 250, to be withdrawn from the first proximal retaining means 224, i.e., the suture loop 252, and allows the restrained stent or stents 130, and the proximal end 108 of the main body prosthesis 120 as a whole, to self-expand radially to the first stage deployment configuration, as seen in Fig. 62. The proximal end 108 of the main body prosthesis 120 desirably radially expands either partially or fully toward the internal walls of the vessel or hollow body organ.

At this point in the deployment process, both the proximal and distal ends of the main body prosthesis 120 are being held and controlled, respectively, by the second proximal retaining means 226 and the distal retaining means 232. This allows the practitioner to adjust the position of the main body prosthesis 120 either longitudinally or rotationally before the next stage (fasten proximal end), as well as hold and maintain control of the main body prosthesis 120 during the next stage (fasten proximal means). Further, because the main body prosthesis 120 can be selectively retained and controlled from both proximal and distal ends during deployment and anchoring, the prosthesis 120 itself need not be self-supporting, but can instead be compliant in either or both longitudinal and/or rotational dimensions, and thereby be capable of conforming and accommodating anatomic changes that may occur after implantation (e.g., shrinkage of the aneurysm).

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D. Fasten Proximal End

The fourth general stage comprises fastening the proximal end 108 of the main body prosthesis 120 to the internal walls of the vessel or hollow body organ. From the right femoral artery, under image guidance, a second guide wire 40 is advanced using a conventional intravascular approach into the contralateral iliac artery and to the descending aorta. However, other access sites and methods can be utilized. The guide wire 40 desirably extends through the second expanded lumen 128 and through the proximal opening 122 of the main body prosthesis 120 (see Fig. 63). Next, the steerable guide device 450, with the obturator 458 positioned within the interior guide passage 456, is then navigated over the second guide wire 40 to the desired location with respect to the main body prosthesis 120 (see Fig. 64). Once the steerable guide device 450 is in position, the obturator 458 and the second guide wire 40 are both removed from the interior guide passage 456 and from the body.

By rotating the steering assembly 460 (see Fig. 55), and still employing fluoroscopy visualization, the clinician deflects the proximal end region 464 - and rotates the handle 454 to rotate the flexible guide tube 452 if necessary - to orient the proximal opening 468 of the passage 456 in a desired facing relationship with the site where introduction of a fastener 402 is desired. An operative tool, such as the fastener device 400 is then inserted through the interior guide passage 456 of the steerable guide device 450, and advanced until a fastener, such as the fastener 402, is located for deployment in relation to the now-oriented proximal opening 468, as Fig. 65 shows. As the fastener device 400 is advanced out of the steerable guide device 450 and contacts the wall of the main body prosthesis 120, a resultant force is applied to the proximal end 464 of the

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steerable guide 450 which moves in the opposite direction of the fastener device proximal end 410. The resultant force causes the proximal end 464 of the steerable guide 450 to deflect until it contacts the opposite wall of the main body prosthesis within the lumen or hollow body organ. In this way, the force applied to the main body prosthesis 120 and vascular wall from the proximal end 410 of the fastener device 400 is partially resolved through the steerable guide 450 within the vessel or hollow body organ. A representative embodiment of an endovascular device that, in use, applies a helical fastener is described in U.S. Patent Application No. 10/786,465, filed February 25, 2004, and entitled "Systems and Methods for Attaching a Prosthesis Within a Body Lumen or Hollow Organ," which is incorporated herein by reference.

The fastener device 400 can then be actuated to apply a fastener 402 to the proximal end 108 of the main body prosthesis 120 and into the surrounding tissue (see Fig. 66). If the fastener device 400 is a single fire device, i.e., it carries only one fastener 402, the fastener device 400 is withdrawn through the interior guide passage 456 and a new fastener 402 is mounted. See Figs 85 and 86 for one embodiment of the fastener 430 being mounted to the fastener device 400. The proximal end region 464 of the steerable device 450 is reoriented in facing relationship with a new fastening site. The fastener device 400 is inserted back through the interior guide passage 456 to apply a second fastener 402 to the new fastening site (see Fig. 67). This sequence is repeated until a desired number and array of fasteners 402 are applied to the main body prosthesis 120, as can be seen in Fig. 68.

At this point, the fastener device 400 is withdrawn, leaving the steerable guide device 450 in place. The

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obturator 458 is repositioned within the interior guide passage 456, and the second guide wire 40 is navigated through the obturator lumen 470 to the desired location with respect to the main body prosthesis 120. Once the second guide wire 40 is in position, the steerable guide device 450 and the obturator 458 are both removed from the interior guide passage 456 and from the body leaving the second guide wire 40 in position within the vasculature.

Throughout this stage of the deployment process, both the proximal and distal ends of the main body prosthesis 120 can be held and controlled, respectively, by the second proximal retaining means 226 and the distal retaining means 232, while fastening occurs.

E. Position First Lumen Extension

In the fifth general stage of the deployment process, following the fastening of the proximal end 108 of the main body prosthesis 120, the extension deployment catheter 350 is used to position a lumen extension 140 for deployment within a lumen of the main body prosthesis 120. From the left or right femoral artery, under image guidance, the extension catheter 350 is navigated over the second guide wire 40 to the desired location, i.e., telescopically positioned partially within the second lumen 128 of the main body prosthesis 120, as Fig. 69 shows. A conventional hemostatic valve arrangement may be used at the access site (shown for purposes of illustration in Fig. 44B).

F. Retract Extension Catheter Outer Jacket

Next, the extension catheter's outer jacket 360 must be retracted in a distal or caudal direction to expose the lumen extension 140. The jacket sliding knob 382 on the extension catheter handle 362 is urged in a distal direction to retract the jacket 360 and fully expose the

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lumen extension 140. The unrestrained portion or portions of the lumen extension 140 self-expand (see Fig. 70). Both during and after retraction of the outer jacket 360, the lumen extension 140 maintains its position relative to the central shaft 356 due to the proximal retaining means 366, coupled to the lumen extension 140.

G. Release Lumen Extension Proximal Retaining Means

In the seventh general step of the deployment process, following the withdrawal of the extension catheter outer jacket 360, the proximal sliding knob 382 on the extension catheter handle assembly 362 is moved distally, which causes the proximal end of the proximal releasing means 370, i.e., the proximal release wire 380, to be withdrawn from the proximal retaining means 366, i.e., the suture loop 378, and allows the restrained stent or stents 150, and the proximal end 142 of the lumen extension 140, to self-expand radially to the deployment configuration, as seen in Figs. 70 and 71. The proximal end 142 of the lumen extension 140 desirably enlarges to contact the internal walls of the second lumen 128 of the main body prosthesis 140. The natural flow of fluid through the lumen extension 140 provides sufficient force to cause the restraint mechanism of the lumen extension 140 to engage the co-acting restraint mechanism of the main body prosthesis 120. The lumen extension stent and/or outwardly extending apices 147 of the lumen extension stent 150 engage the mating outwardly extending apices 136 of the distal stent 134 positioned within the second lumen 128 of the main body prosthesis 120 (as best seen in Fig. 10B) in order to couple the lumen extension 140 to the main body prosthesis 120.

Prior to withdrawing the extension catheter 350, the outer jacket 360 is desirably repositioned in an abutting relationship with the catheter tip 368. The jacket

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sliding knob 382 on the extension catheter handle 362 is urged in a proximal direction to reposition the jacket 360 in a pre-deployment configuration. The extension catheter 350 may now be withdrawn and removed from the body. The second guide wire 40 may either be removed, or
5 may remain until the deployment process is completed.

H. Release Second Proximal Retaining Means

In the eighth general stage of the deployment process, following the deployment of a first lumen extension 140, the second proximal retaining means 226 is released. To release the proximal end 108 of the main
10 body prosthesis 120, the second proximal release sliding knob 324 on the handle 212 is moved distally, which causes the proximal end of the second proximal releasing means 230, i.e., the second proximal release wire 268, to be withdrawn from the prosthesis material 112 and the stabilizing arm apertures 264, and allows the stabilizing arms 256 to release from the proximal end 108 of the main body prosthesis 120, and spring proximally, as shown in
15 Fig. 72. The proximal end 108 of the main body prosthesis 120 is no longer in a restrained relationship with the central shaft 216.

I. Release Distal Retaining Means

In the ninth general stage of the deployment process, following the release of the second proximal retaining means 226, the distal retaining means 220 is released. To release the distal end 110 of the main body prosthesis 140, the distal release sliding knob 326 on the handle 212 is moved distally, which causes the
25 proximal end of the distal releasing means 232, i.e., the distal release wire 282, to be withdrawn from the distal retaining means 220, i.e., the distal suture loop 274, and allows the restrained stent or stents 134 to self-expand radially to the second stage deployment configuration, as seen in Fig. 73. As previously
35

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mentioned, alternatively, the stent or stents 140 are not necessarily radially restrained by the distal retaining means 226. The main body prosthesis 120 is no longer in a restrained relationship with the central shaft 216.

5 Prior to withdrawing the deployment catheter 200, the outer jacket 210 is desirably repositioned in an abutting relationship with the catheter tip 222. The jacket sliding knob 294 on the catheter handle 212 is urged in a proximal direction to reposition the jacket
10 210 in a pre-deployment configuration. The deployment catheter 200 may now be withdrawn from the body, leaving the first guide wire 30 within the vasculature (see Fig. 74).

J. Position Second Lumen Extension

15 In the tenth general stage of the deployment process, following the release of the distal retaining means 220 and withdrawal of the deployment catheter 200, the second lumen extension 140 is positioned for deployment. The general steps as describe for the
20 deployment of the first lumen extension 140 are the same or similar, but will be repeated here for clarity. The extension deployment catheter 350 is again used to position the second lumen extension 140 for deployment within a lumen of the main body prosthesis 120. From the
25 left or right femoral artery, for example, under image guidance, the extension catheter 350 is navigated over the first guide wire 30 to the desired location, i.e., telescopically positioned partially within the first lumen 126 of the main body prosthesis 120, as Fig. 75
30 shows. Again, as previously described, a conventional hemostatic valve arrangement may be used at the access site (shown for purposes of illustration in Fig. 44B).

K. Retract Extension Catheter Outer Jacket

35 Next, the extension catheter's outer jacket 360 must be retracted in a distal or caudal direction to expose

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the lumen extension 140. The jacket sliding knob 382 on the extension catheter handle 362 is urged in a distal direction to retract the jacket 360 and fully expose the lumen extension 140. The unrestrained portion or portions of the lumen extension 140 self-expand (see Figs. 75 and 76). As Fig. 76 shows, both during and after retraction of the outer jacket 360, the lumen extension 140 maintains its position relative to the central shaft 356 due to the proximal retaining means 366, coupled to the lumen extension 140.

L. Release Lumen Extension Proximal Retaining Means

In the twelfth general step of the deployment process, following the withdrawal of the extension catheter outer jacket 360, the proximal sliding knob 382 on the extension catheter handle assembly 362 is moved distally, which causes the proximal end of the proximal releasing means 370, i.e., the proximal release wire 380, to be withdrawn from the proximal retaining means 366, i.e., the suture loop 378, and allows the restrained stent or stents 150, and the proximal end 142 of the lumen extension 140, to self-expand radially to the deployment configuration, as seen in Fig. 77. The proximal end 142 of the lumen extension 140 desirably enlarges to contact the internal walls of the first lumen 126 of the main body prosthesis 140. The natural flow of fluid through the lumen extension 140 provides sufficient force to cause the restraint mechanism of the lumen extension 140 to engage the co-acting restraint mechanism of the main body prosthesis 120. The lumen extension stent and/or the outwardly extending apices 147 of the lumen extension stent 150 engage the mating outwardly extending apices 136 of the distal stent 134 positioned within the first lumen 126 of the main body prosthesis 120 (as best seen in Fig. 10B) in order to couple the

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lumen extension 140 to the main body prosthesis 120.

Prior to withdrawing the extension catheter 350, the outer jacket 360 is desirably repositioned in an abutting relationship with the catheter tip 368. The jacket
5 sliding knob 382 on the extension catheter handle 362 is urged in a proximal direction to reposition the jacket 360 in a pre-deployment configuration. The extension catheter 350 may now be withdrawn and removed from the body. Both the first guide wire 30 and the second guide
10 wire 40 may now be removed to complete the deployment process of the bifurcated prosthesis 100, as can be seen in Fig. 78.

It is to be appreciated that the general steps just described do not necessarily need to follow the order in
15 which they were described. For example, the second proximal retaining means may be released prior to the deployment of the first lumen extension 140, and the second guide wire may be removed prior to the completion of the deployment process. It is also to be appreciated
20 that fasteners may be applied to the lumen extensions as well to connect the lumen extensions to the iliac arteries.

It will also be appreciated that the components and/or features of the preferred embodiments described
25 herein may be used together or separately, while the depicted methods and devices may be combined or modified in whole or in part. It is contemplated that the components of the guiding device, fastener device, and helical fastener may be alternately oriented relative to
30 each other, for example, offset, bi-axial, etc. Further, it will be understood that the various embodiments may be used in additional procedures not described herein, such as vascular trauma, arterial dissections, artificial heart valve attachment and attachment of other prosthetic
35 device within the vascular system and generally within

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the body.

The foregoing is considered as illustrative only of the principles of the invention. Furthermore, since numerous modifications and changes will readily occur to those skilled in the art, it is not desired to limit the invention to the exact construction and operation shown and described. While the preferred embodiment has been described, the details may be changed without departing from the invention, which is defined by the claims.

10 The desired embodiments of the invention are described above in detail for the purpose of setting forth a complete disclosure and for the sake of explanation and clarity. Those skilled in the art will envision other modifications within the scope and spirit
15 of the present disclosure.

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I/We Claim:

1. A fastener applier for securing a prosthesis comprising
a handle assembly positioned at the caudal end of
5 the fastener applier,
a fastener applier shaft coupled to the handle assembly, and
a fastener driver for advancing a fastener into the prosthesis and tissue, the fastener driver coupled to the
10 fastener applier shaft at the cephalad end of the fastener applier shaft, the fastener driver including a housing and a release latch, wherein the release latch prevents premature release of the fastener from the fastener driver.
- 15 2. A fastener applier according to claim 1
wherein the fastener driver housing includes an internally threaded portion and a non-threaded portion, the non-threaded portion providing an area where the fastener can be rotated but not advanced out of the
20 driver, the advancement out of the driver only taking place if the fastener has been previously engaged in tissue or the prosthesis.
3. A fastener applier according to claim 1
wherein the handle assembly further includes a
25 motion control assembly to be used by an operator, the motion control assembly providing motion control of the fastener within the fastener driver.
4. A fastener applier according to claim 3
wherein the motion control assembly includes a
30 forward control function and a reverse control function.
5. A fastener applier according to claim 1
wherein the handle assembly further includes an indication assembly to provide information to an operator, the indication assembly providing at least one
35 of an audible and visual indication.

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6. A fastener applier according to claim 5 wherein the information includes at least one of a fastener position or timing or status or error, or any combination.

5 7. A fastener applier according to claim 1 wherein the fastener is a helical fastener.

8. A fastener applier according to claim 7 wherein the helical fastener includes a fastener body having a distal end for penetrating tissue in
10 response to a force and a proximal end for releasably coupling the fastener body to the fastener applier, and a stop structure associated with the proximal end to prevent over-penetration of the fastener body into tissue, the stop structure bisecting the diameter of the
15 fastener body.

9. A fastener applier according to claim 8 wherein the stop structure is offset from the diameter of the fastener body.

10. An apparatus for storing a fastener for
20 securing a prosthesis comprising a base structure, and at least one receptacle positioned within the base structure, the receptacle sized and configured to releasably store at least one fastener.

25 11. An apparatus according to claim 10 wherein the receptacle is sized and configured to releasably store at least one helical fastener.

12. An apparatus according to claim 11 wherein the helical fastener includes a fastener
30 body having a distal end for penetrating tissue in response to a force and a proximal end for releasably coupling the fastener body to the fastener applier, and a stop structure associated with the proximal end to prevent over-penetration of the fastener body into
35 tissue, the stop structure bisecting the diameter of the

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fastener body.

13. An apparatus according to claim 12
wherein the stop structure is offset from the
diameter of the fastener body.

5 14. An apparatus according to claim 10
wherein the receptacle is sized and configured to
present the fastener to a fastener applier.

15 15. An apparatus according to claim 10
further including a post positioned within the
10 receptacle to releasably restrain the fastener.

16. An apparatus according to claim 10
further including a pliable material within the
receptacle to position a tip of the fastener in the
pliable material to releasably restrain the fastener.

15 17. An apparatus according to claim 10
wherein the fastener is releasably restrained within
the receptacle by friction between the fastener and the
receptacle wall.

18. A method of installing a fastener to a
20 fastener applier comprising

providing an apparatus for storing a fastener, the
apparatus comprising a base structure, and at least one
receptacle positioned within the base structure, the
receptacle sized and configured to releasably store at
25 least one fastener,

providing a fastener applier for securing a
prosthesis, the fastener applier comprising a handle
assembly positioned at the caudal end of the fastener
applier, a fastener applier shaft coupled to the handle
30 assembly, and a fastener driver for advancing a fastener
into the prosthesis and tissue, the fastener driver
coupled to the fastener applier shaft at the cephalad end
of the fastener applier shaft, the fastener driver
including a housing and a release latch, wherein the
35 release latch prevents premature release of the fastener

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from the fastener driver,

positioning the fastener driver so as to allow the
fastener driver to couple to releasably stored fastener,
and

5 coupling the fastener to the fastener applier.

19. A method according to claim 18

wherein coupling the fastener to the fastener
applier includes operating a motion control assembly
positioned on the handle assembly to retract the fastener
10 out of the receptacle and onto the fastener driver.

20. A method according to claim 18

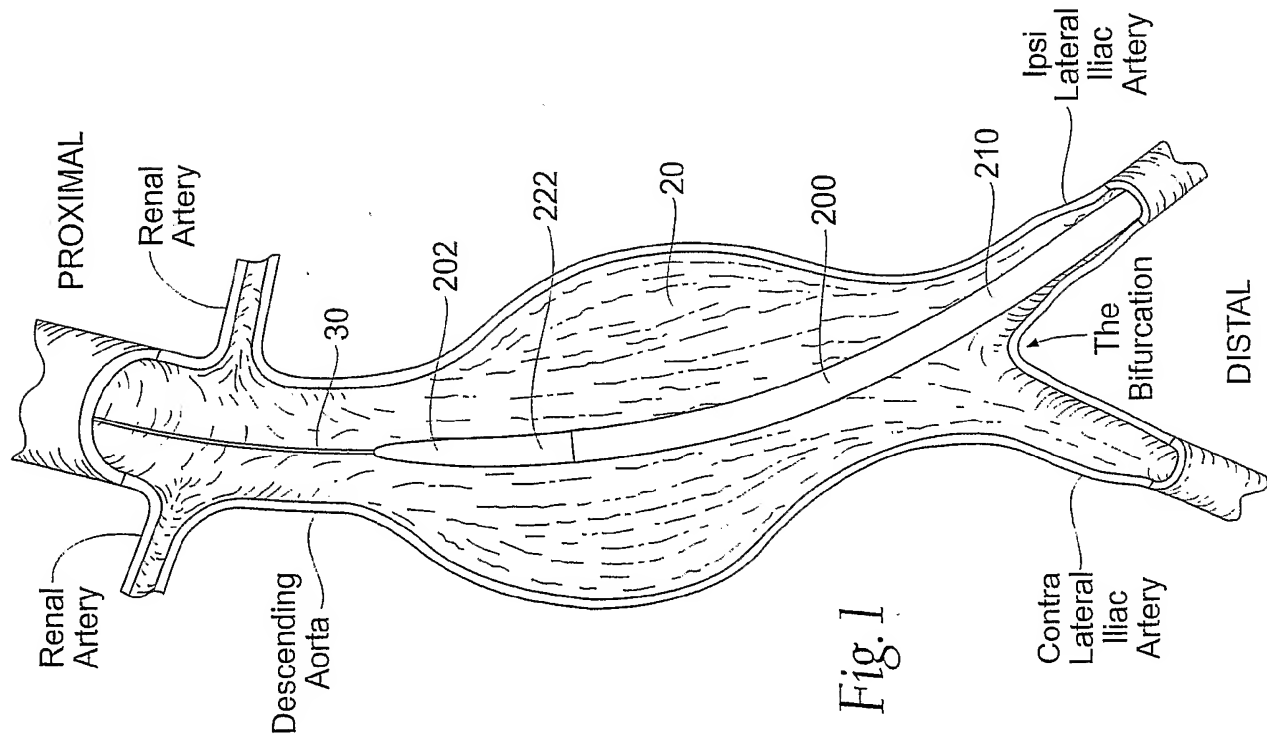
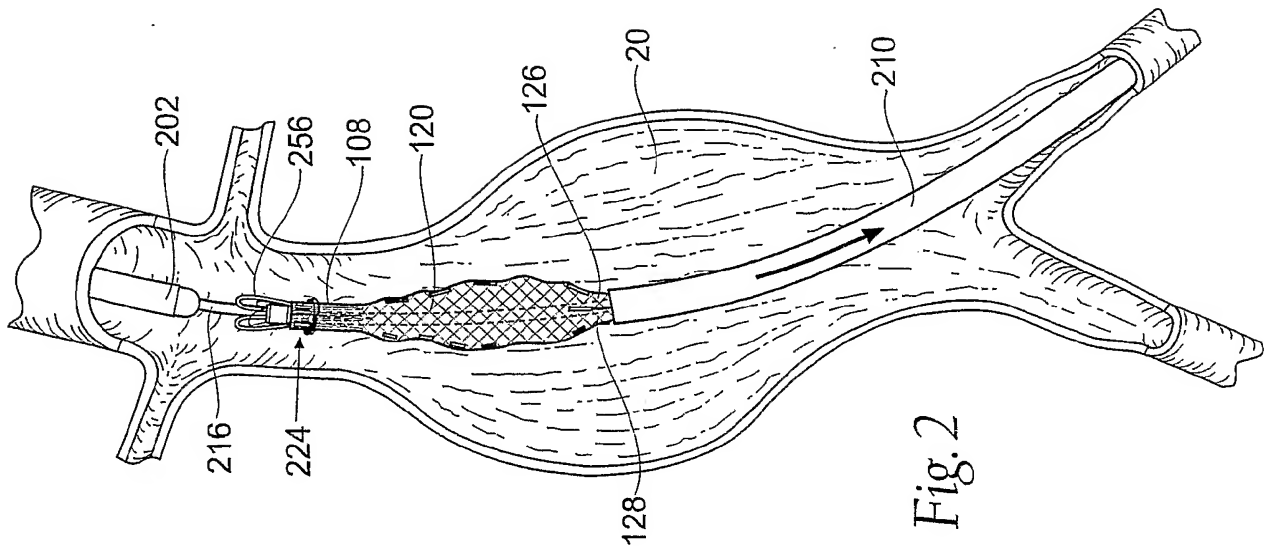
wherein the receptacle is sized and configured to
releasably secure at least one helical fastener.

21. An apparatus according to claim 20

15 wherein the helical fastener includes a fastener
body having a distal end for penetrating tissue in
response to a force and a proximal end for releasably
coupling the fastener body to the fastener applier, and
a stop structure associated with the proximal end to
20 prevent over-penetration of the fastener body into
tissue, the stop structure bisecting the diameter of the
fastener body.

22. An apparatus according to claim 21

wherein the stop structure is offset from the
25 diameter of the fastener body.



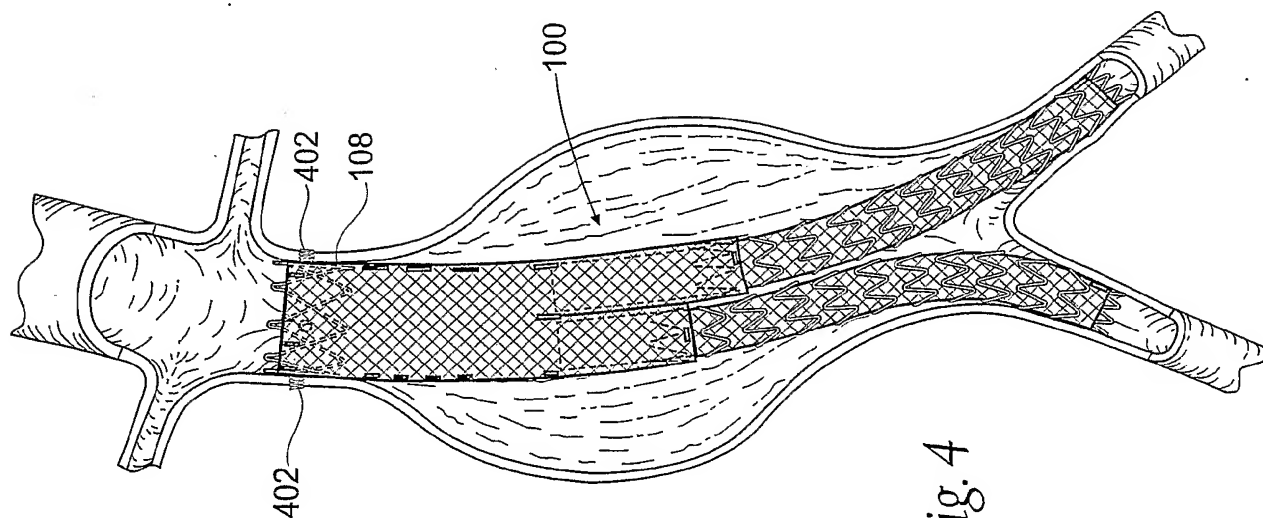


Fig. 4

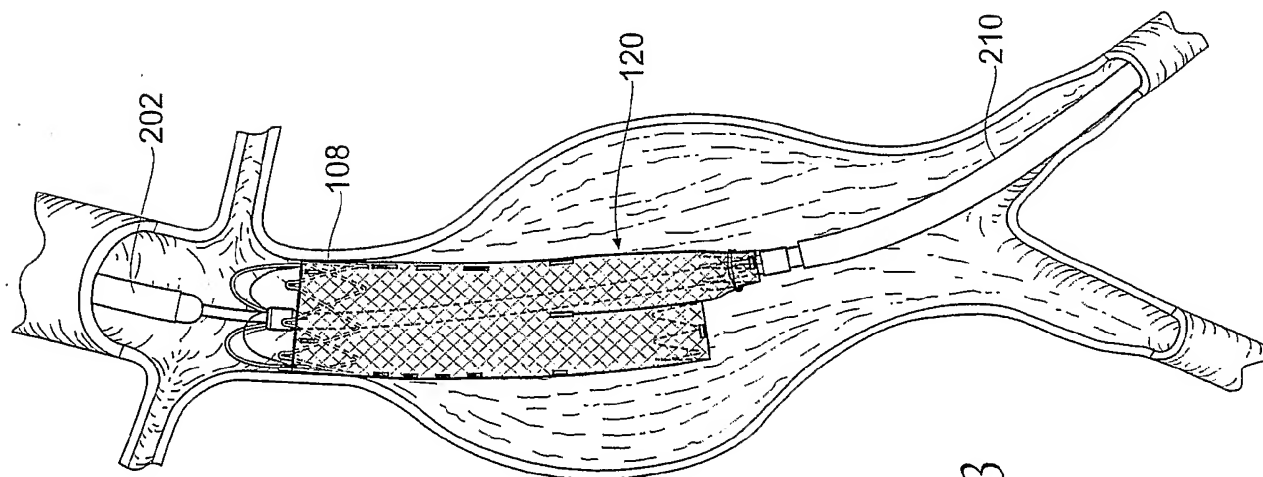


Fig. 3

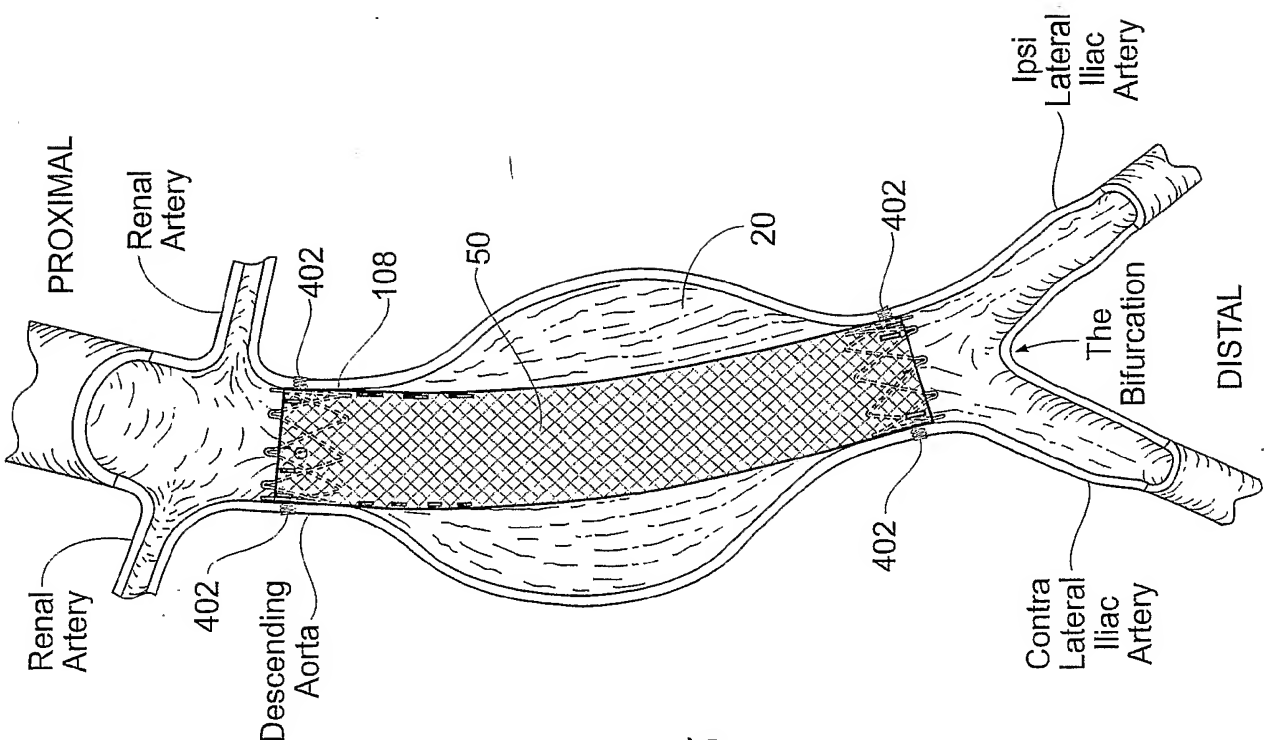
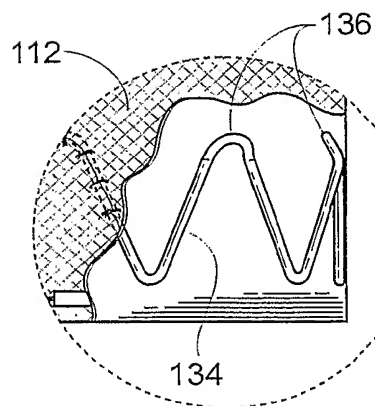
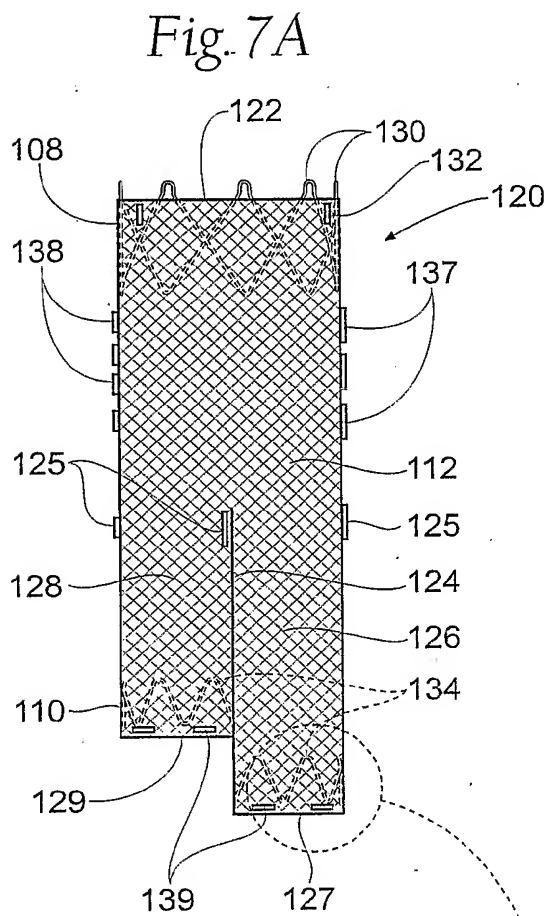
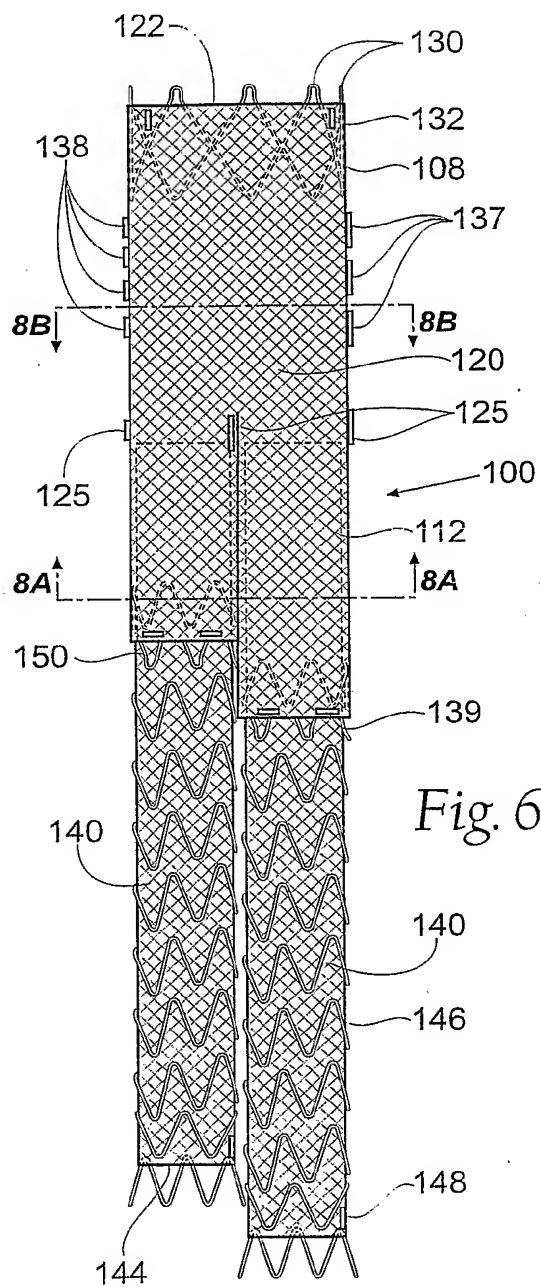


Fig. 5



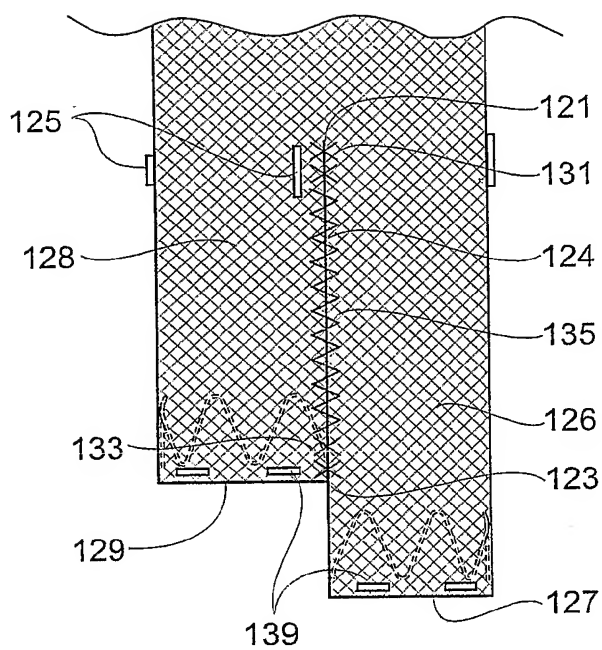


Fig. 7C

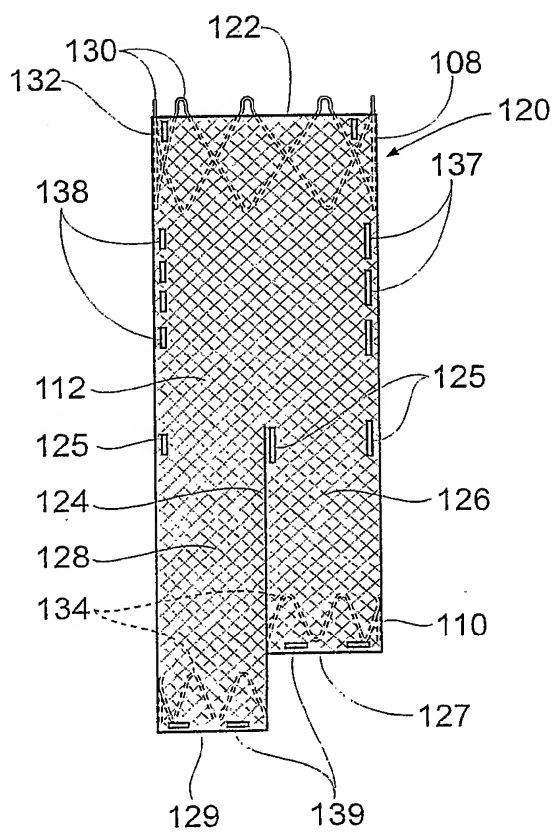


Fig. 7D

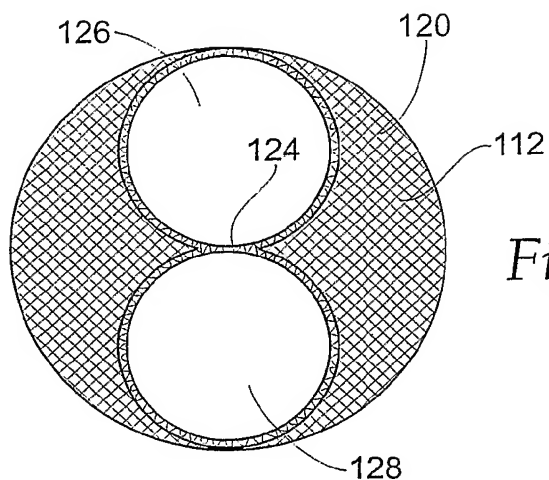


Fig. 8A

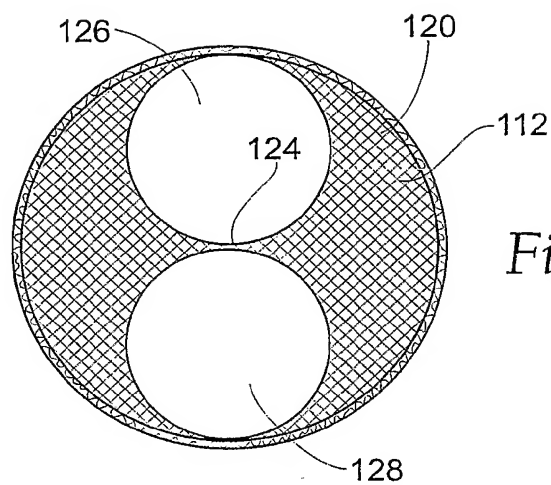


Fig. 8B

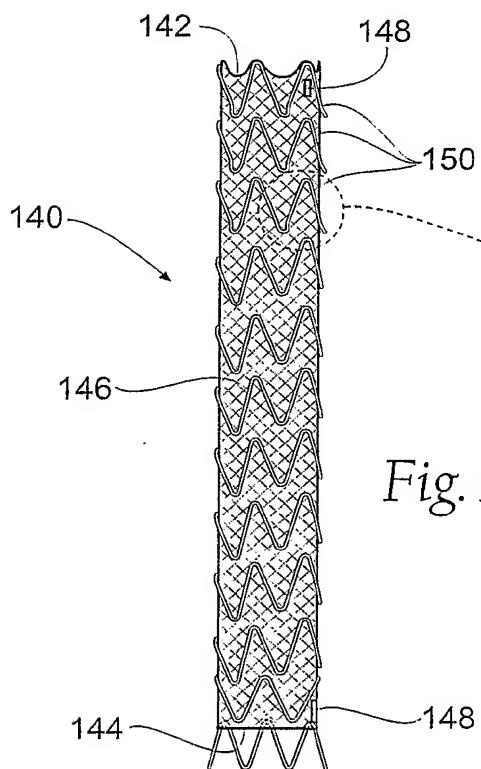


Fig. 9A

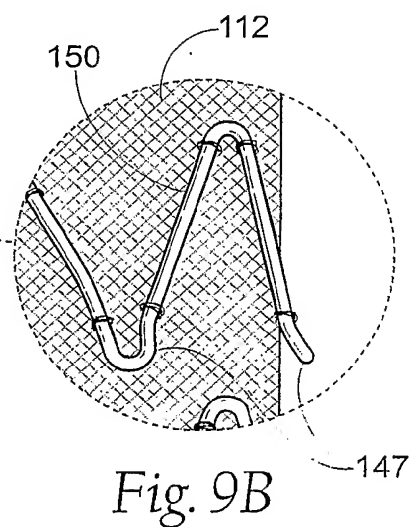


Fig. 9B

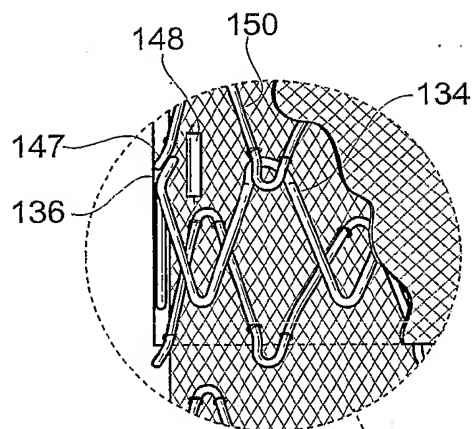


Fig. 9D

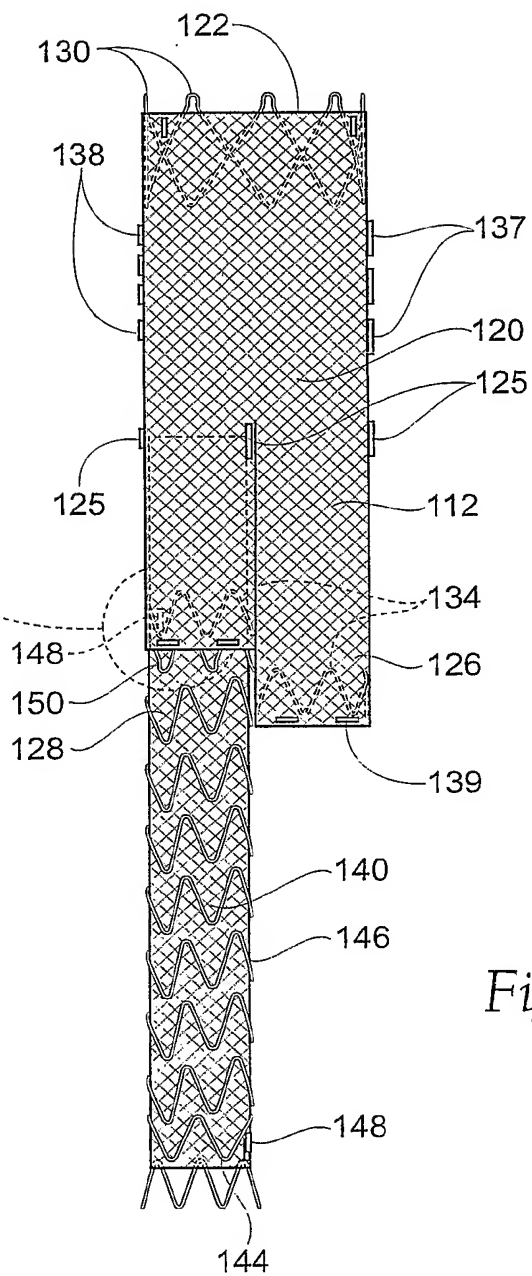


Fig. 9C

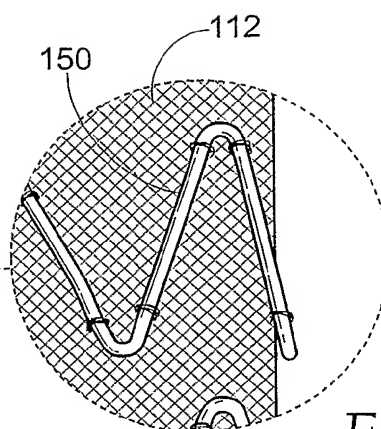
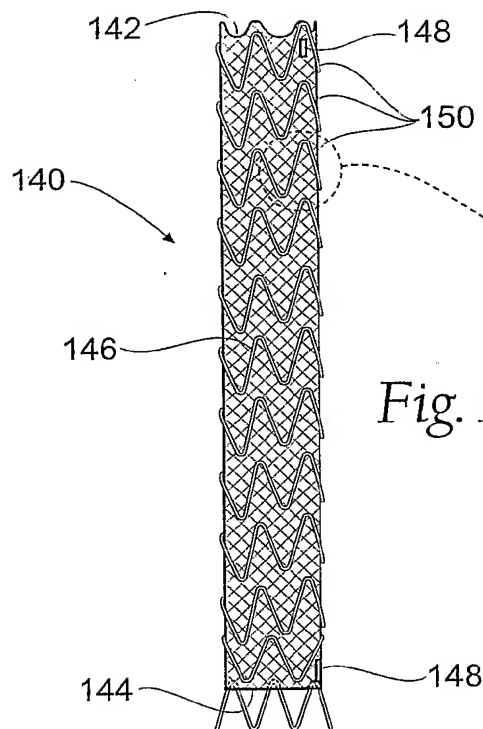
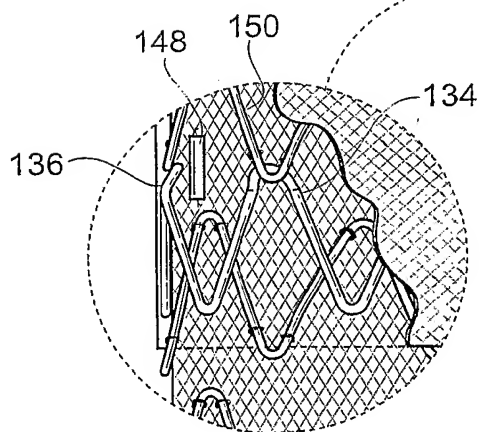
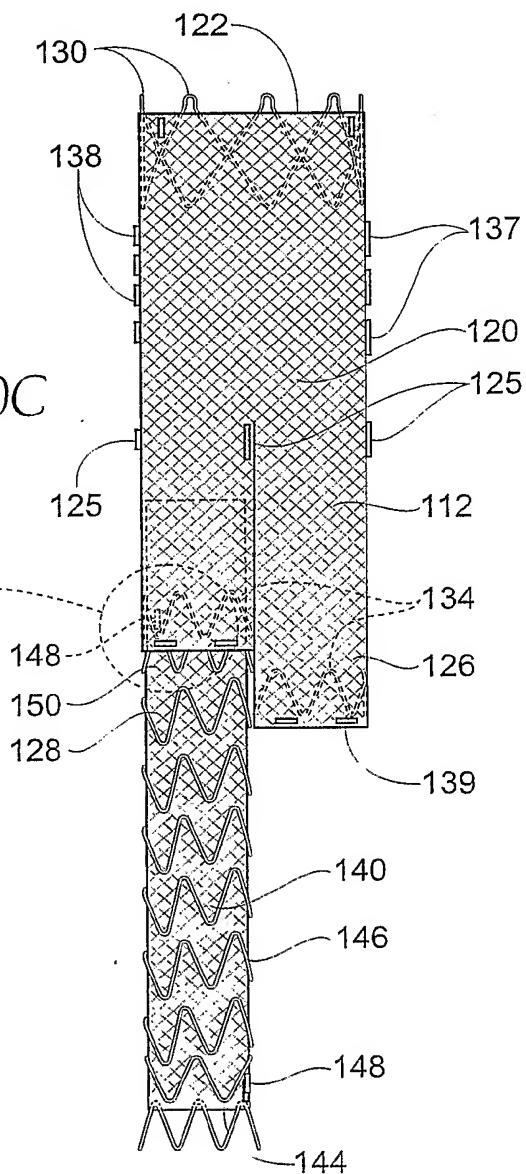
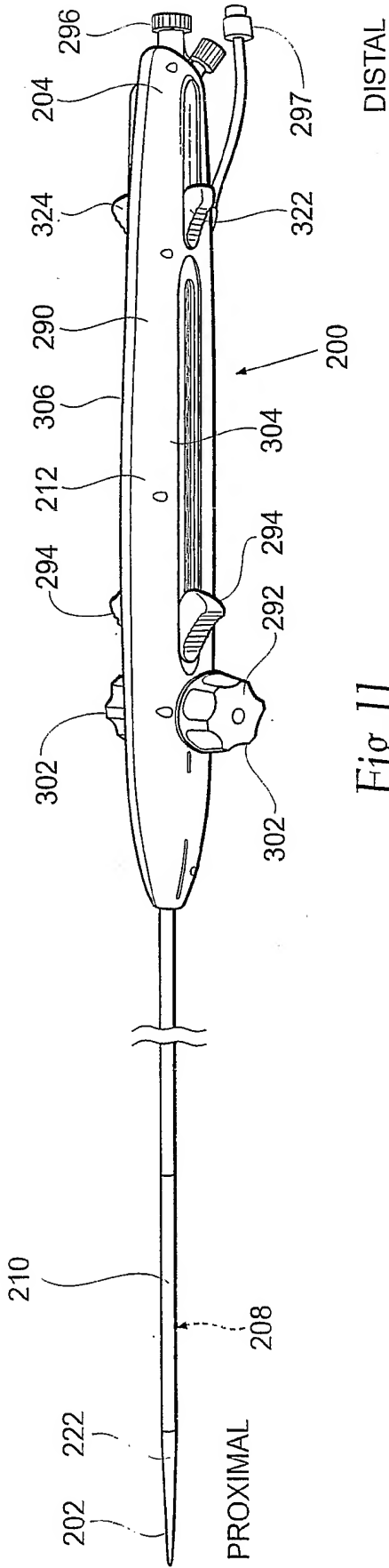
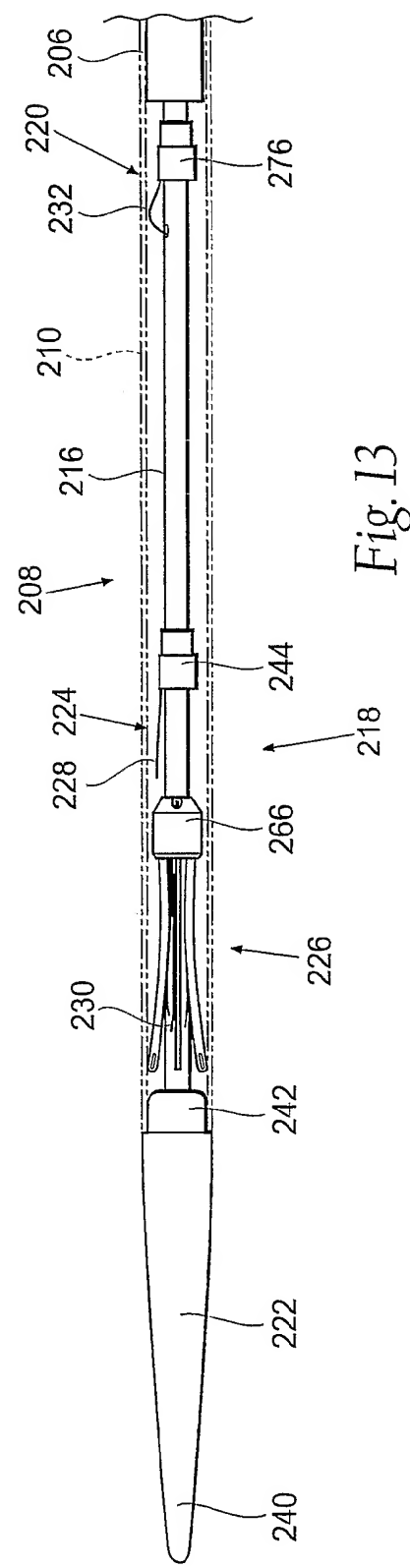
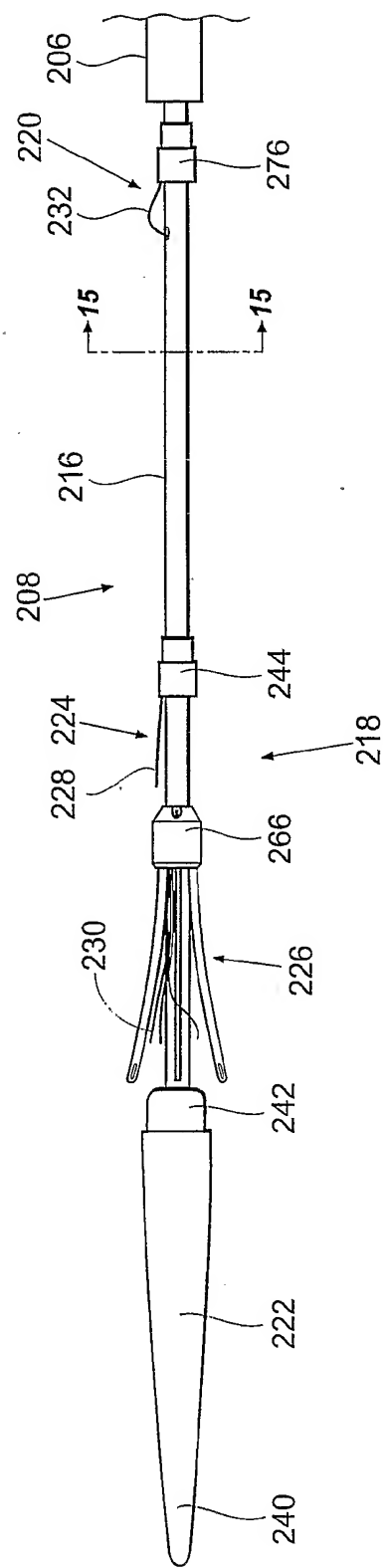


Fig. 10C







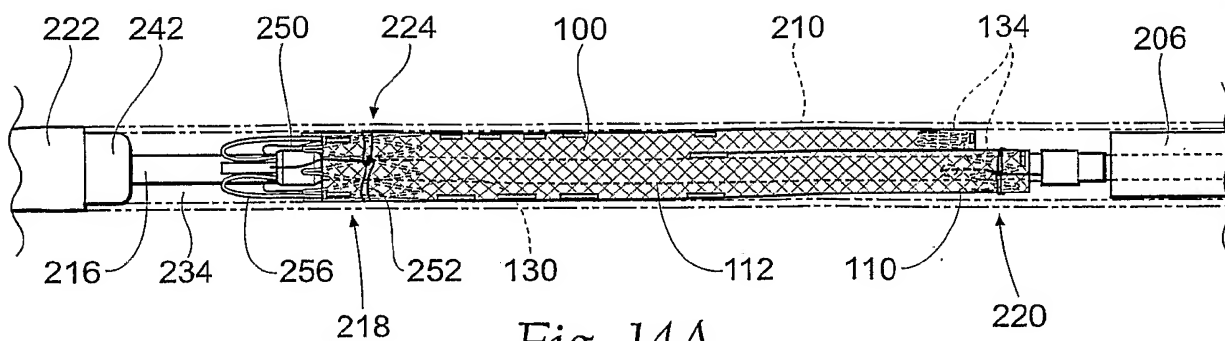


Fig. 14A

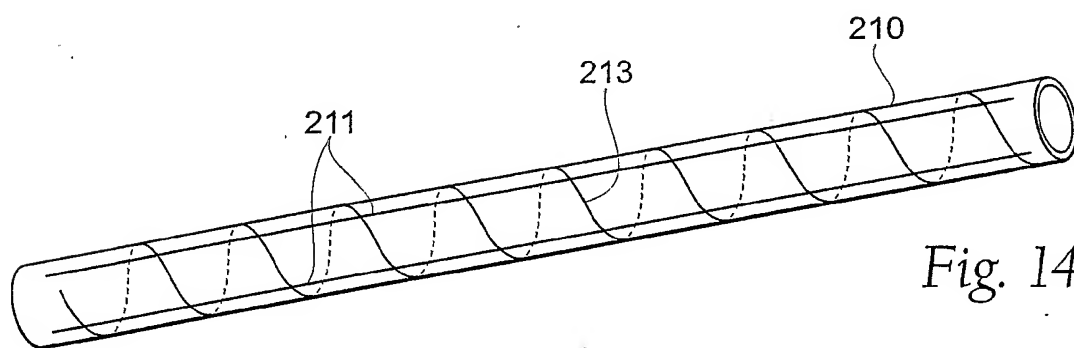


Fig. 14B

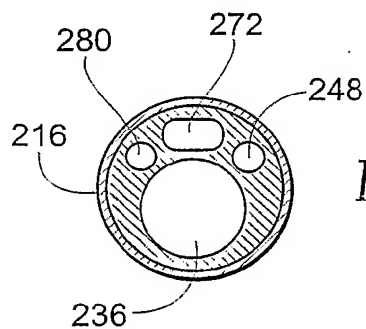
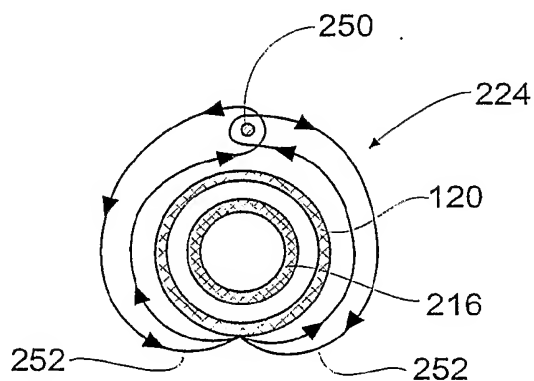
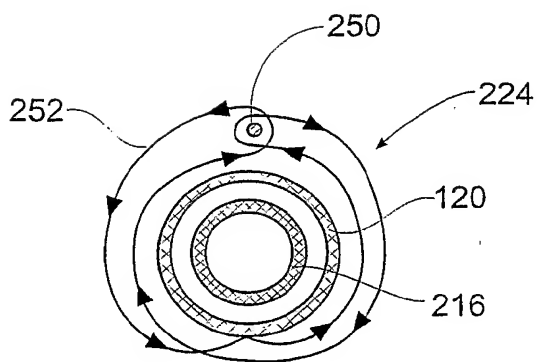
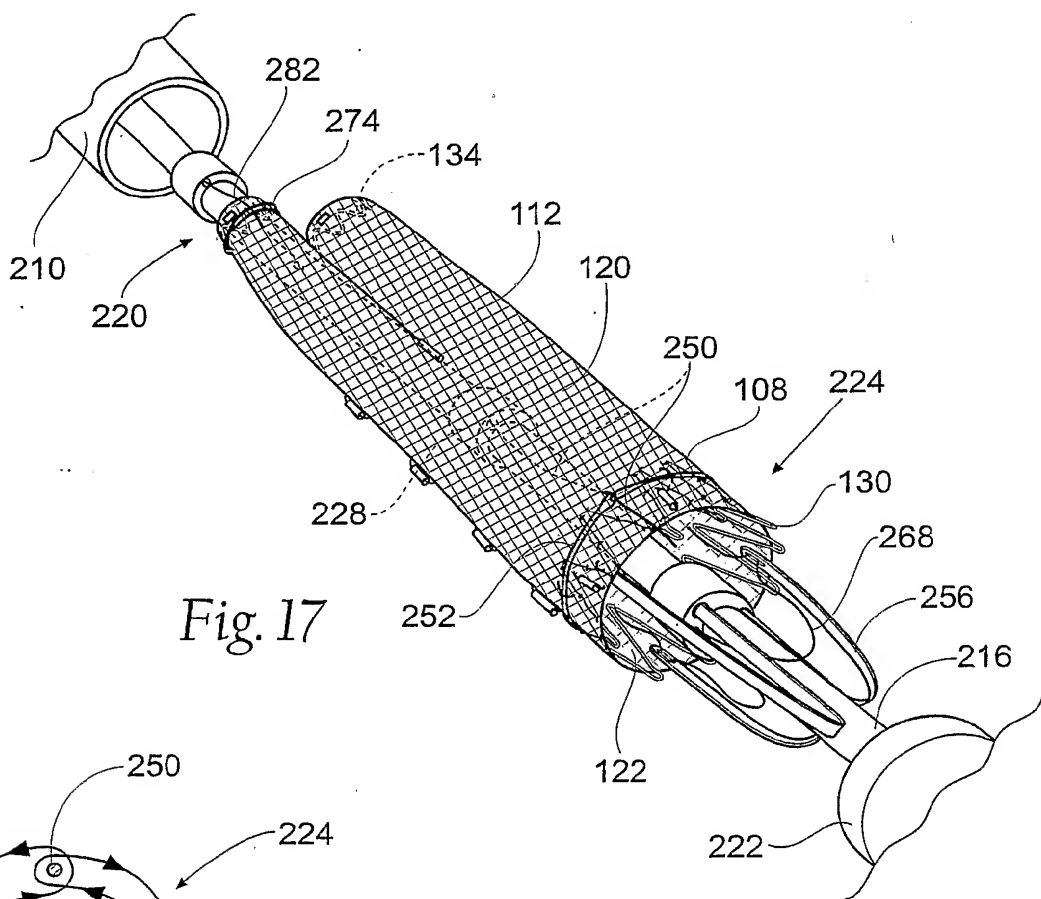
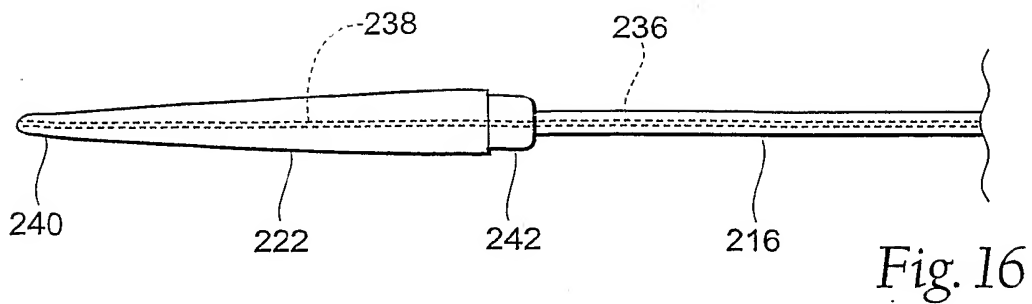
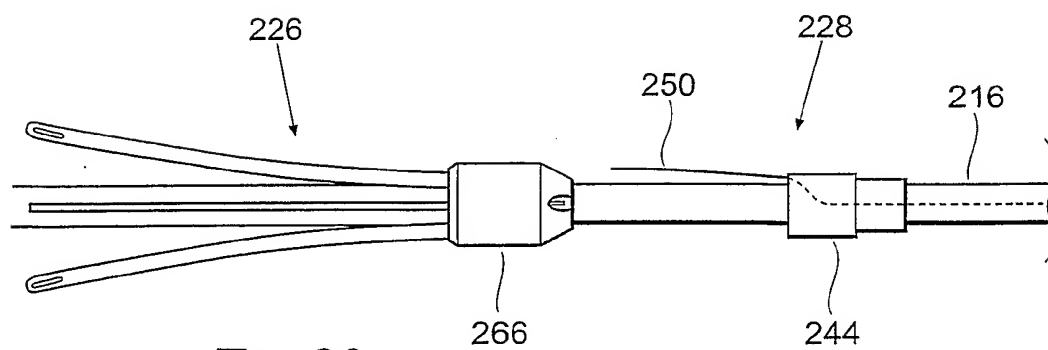
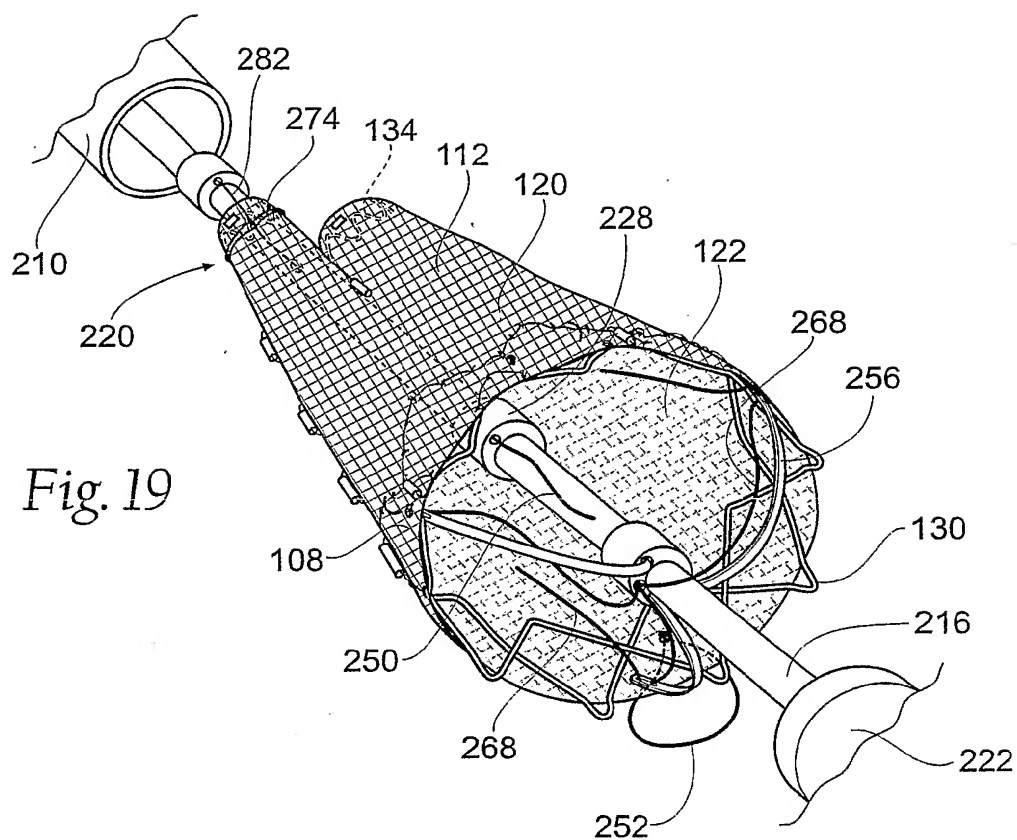


Fig. 15





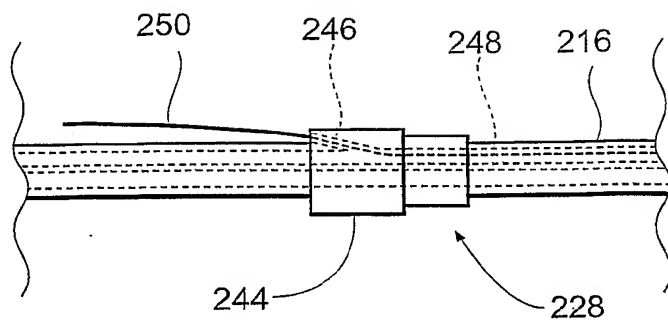


Fig. 21

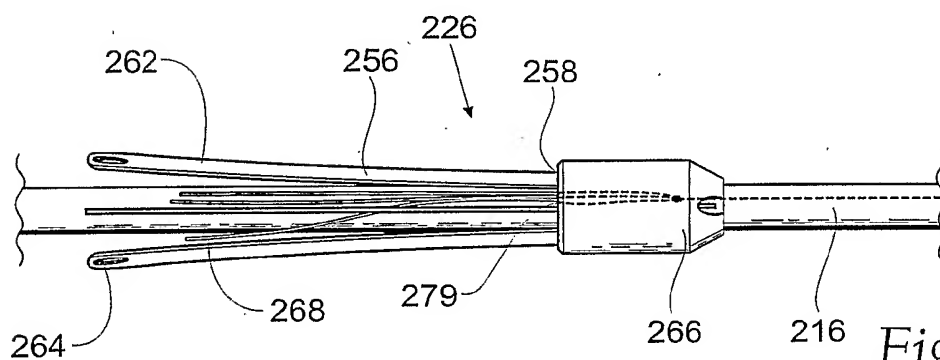


Fig. 22

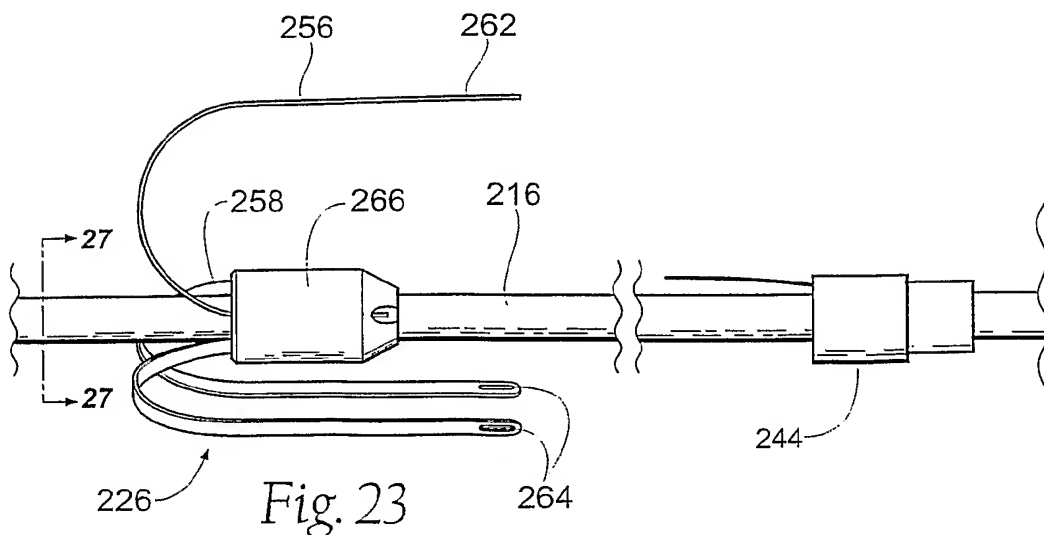


Fig. 23

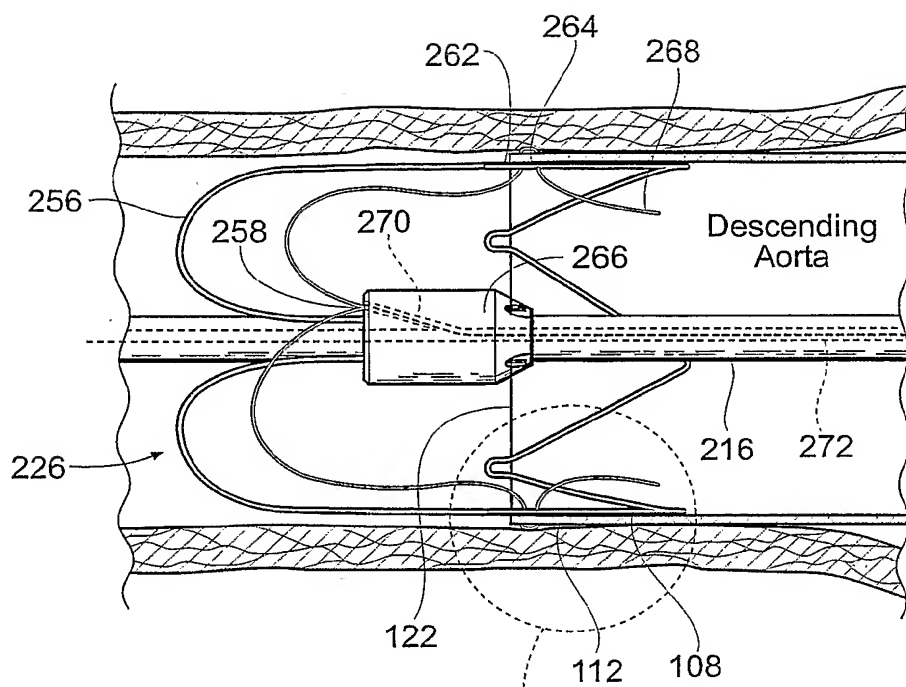


Fig. 24

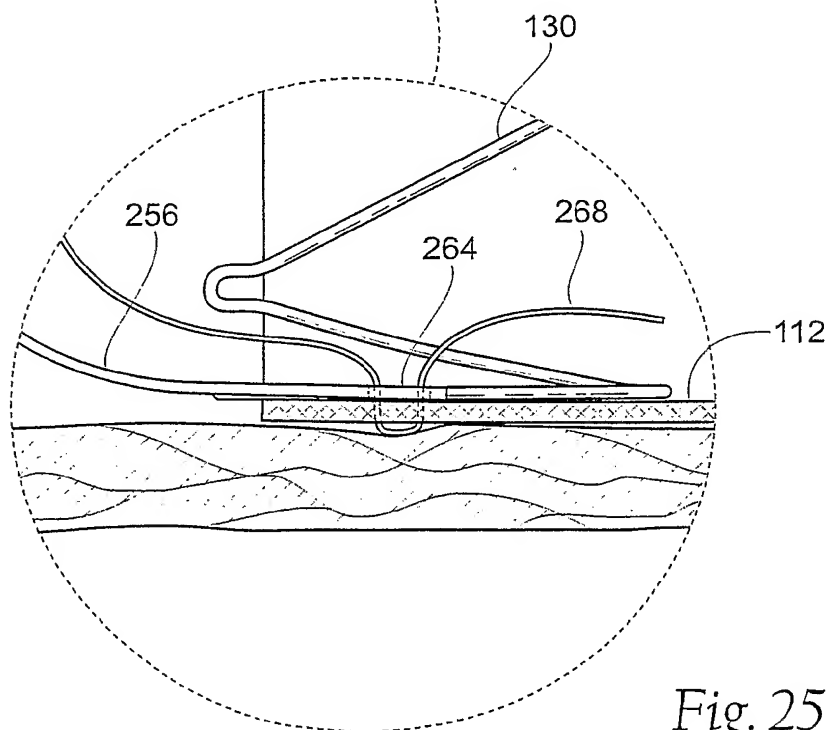


Fig. 25

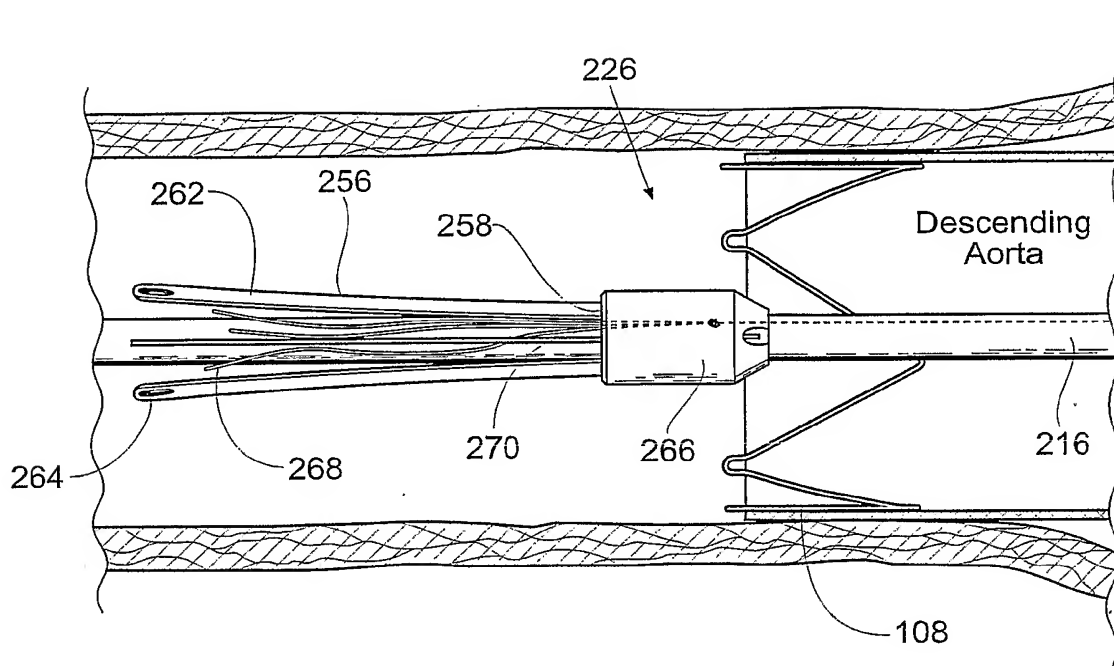


Fig. 26

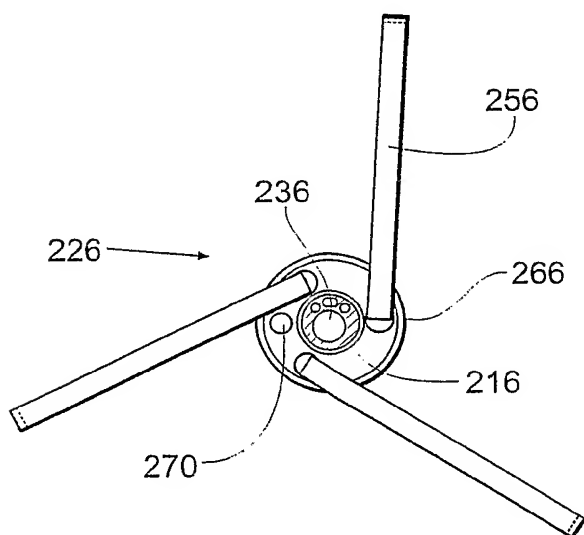


Fig. 27

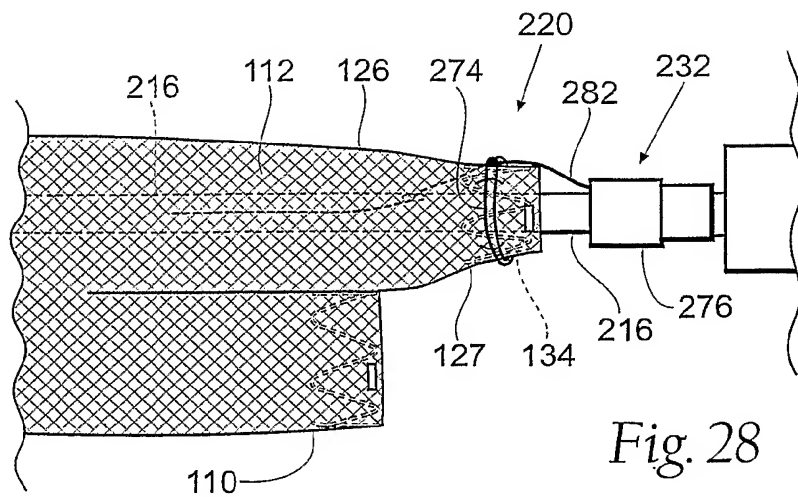


Fig. 28

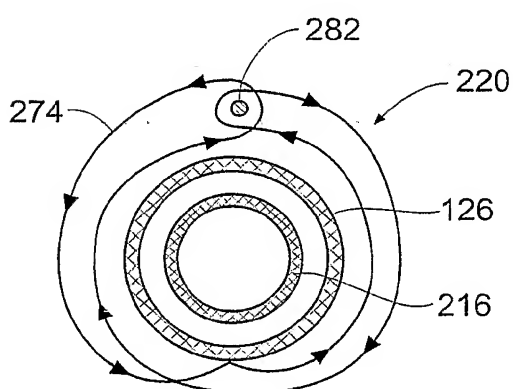


Fig. 29A

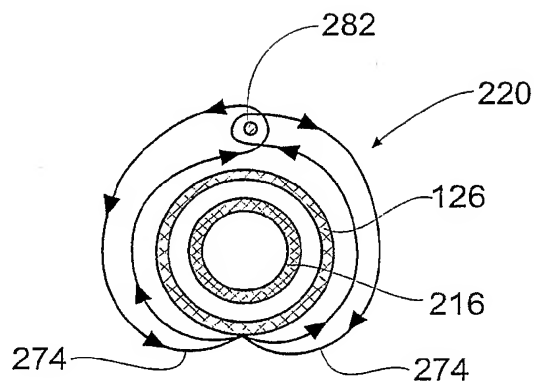


Fig. 29B

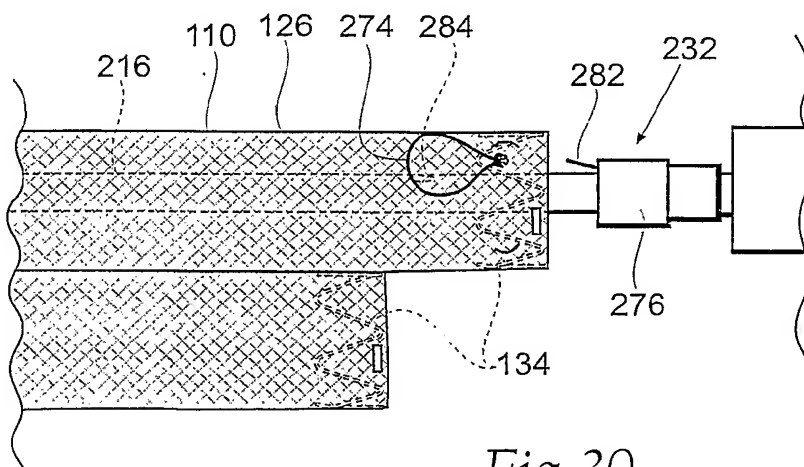


Fig. 30

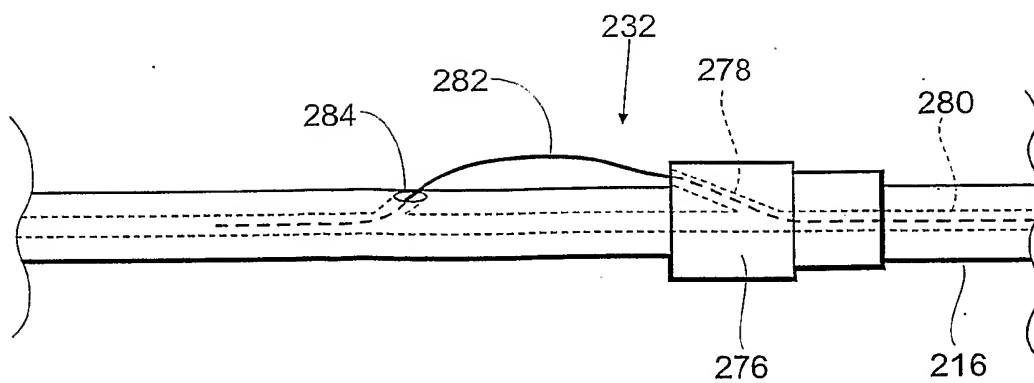


Fig. 31

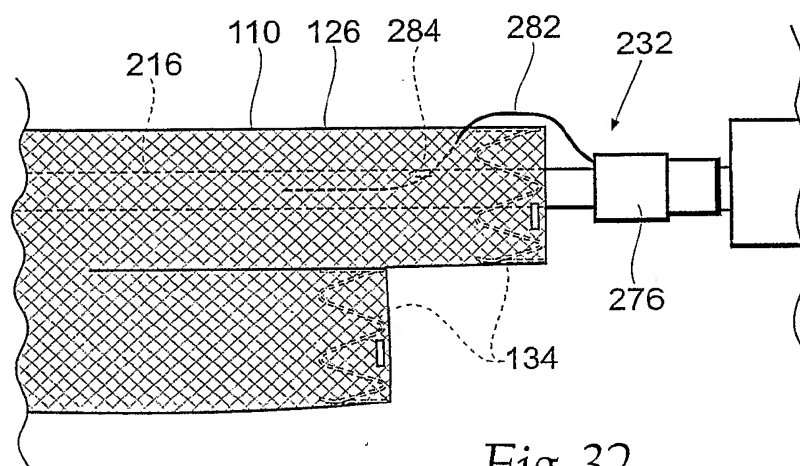


Fig. 32

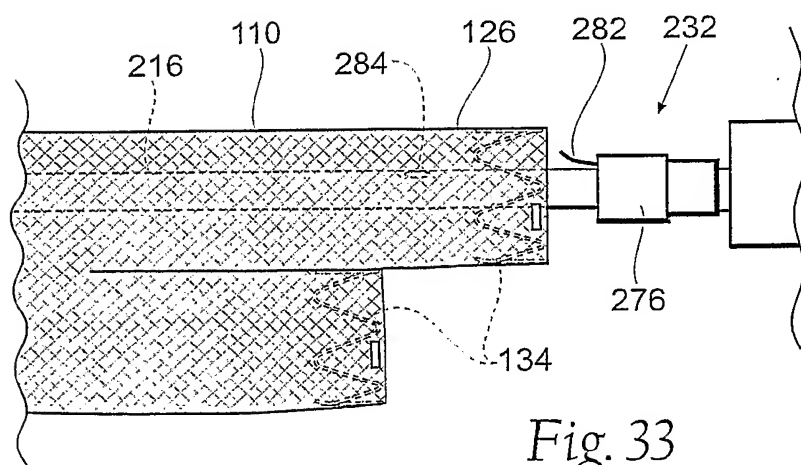


Fig. 33

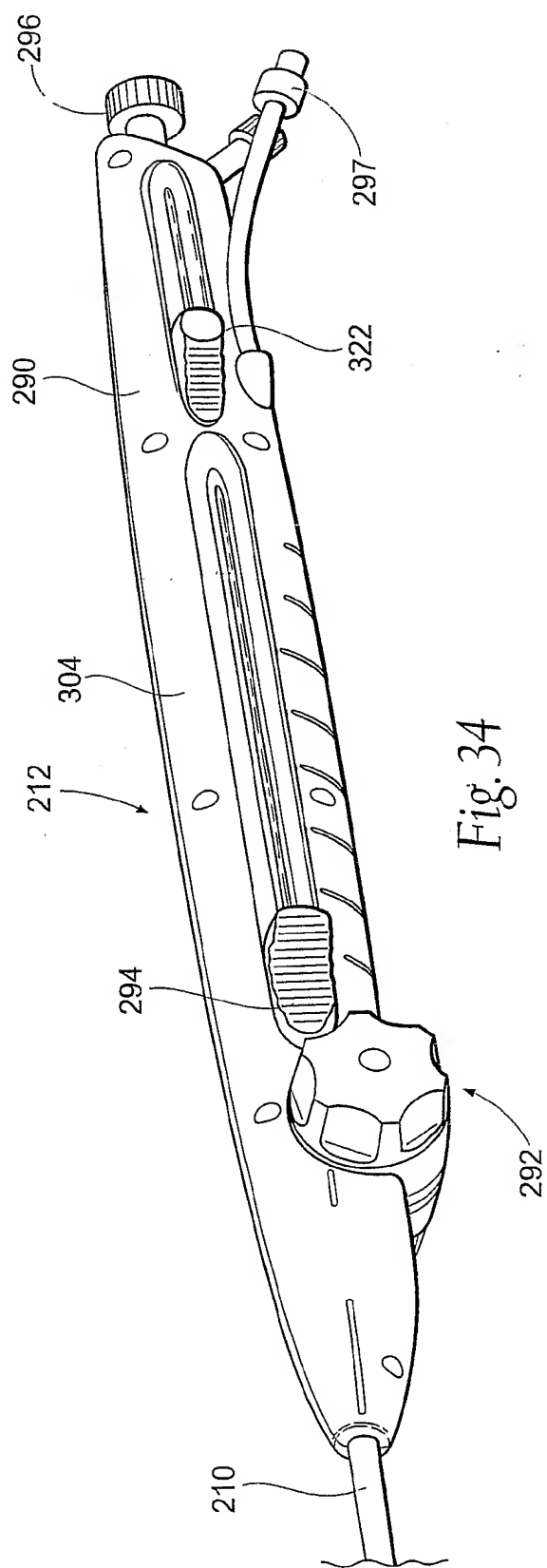


Fig. 34

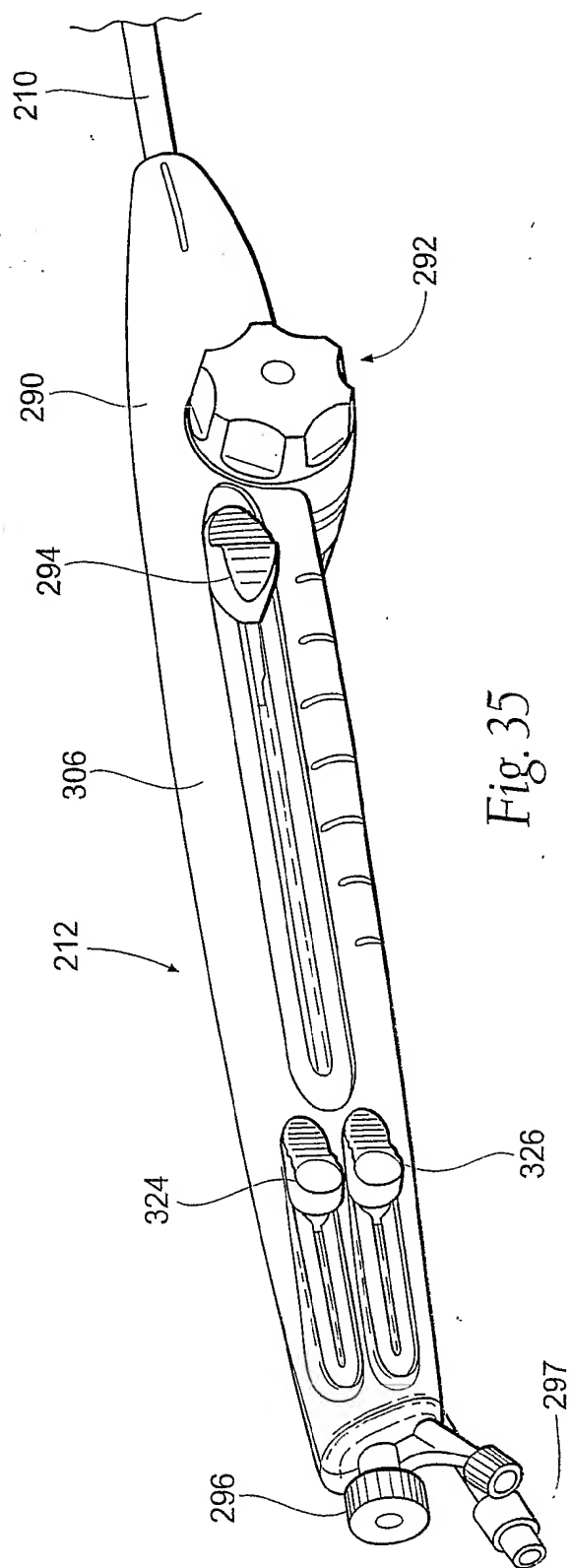


Fig. 35

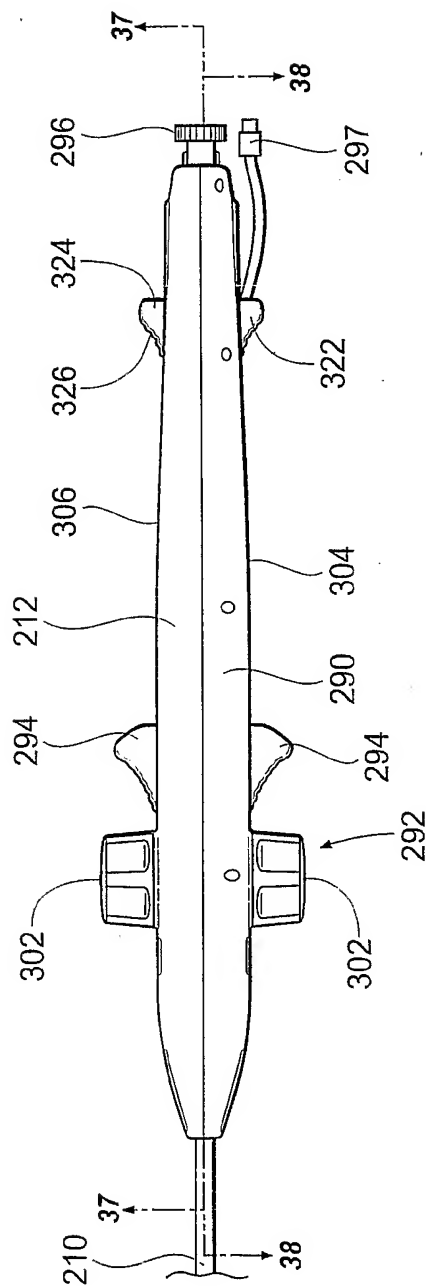


Fig. 36

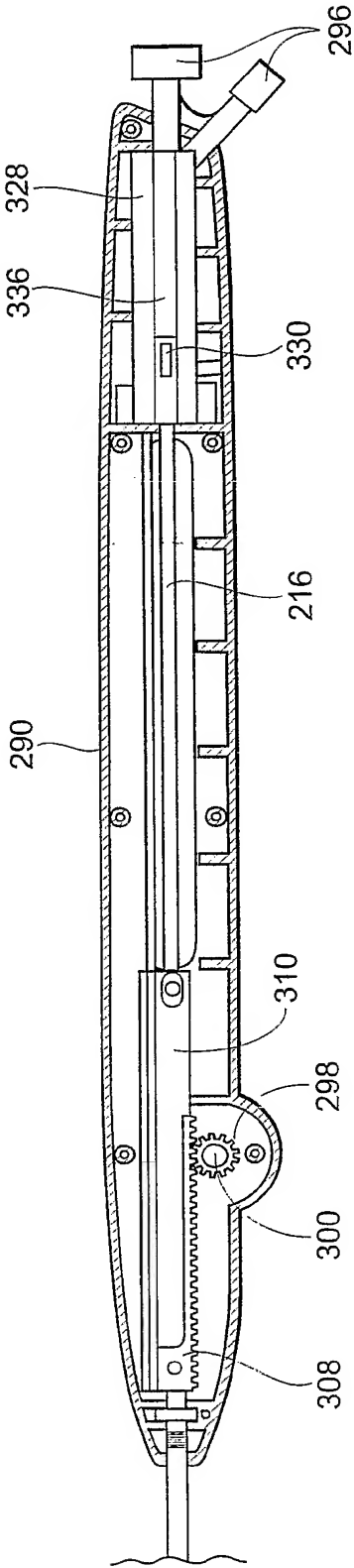


Fig. 37

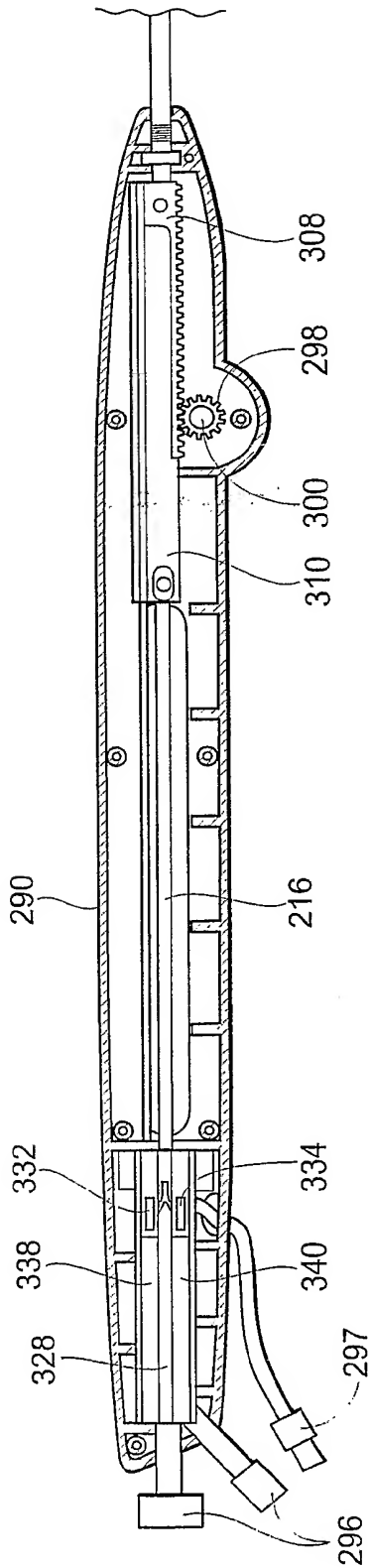
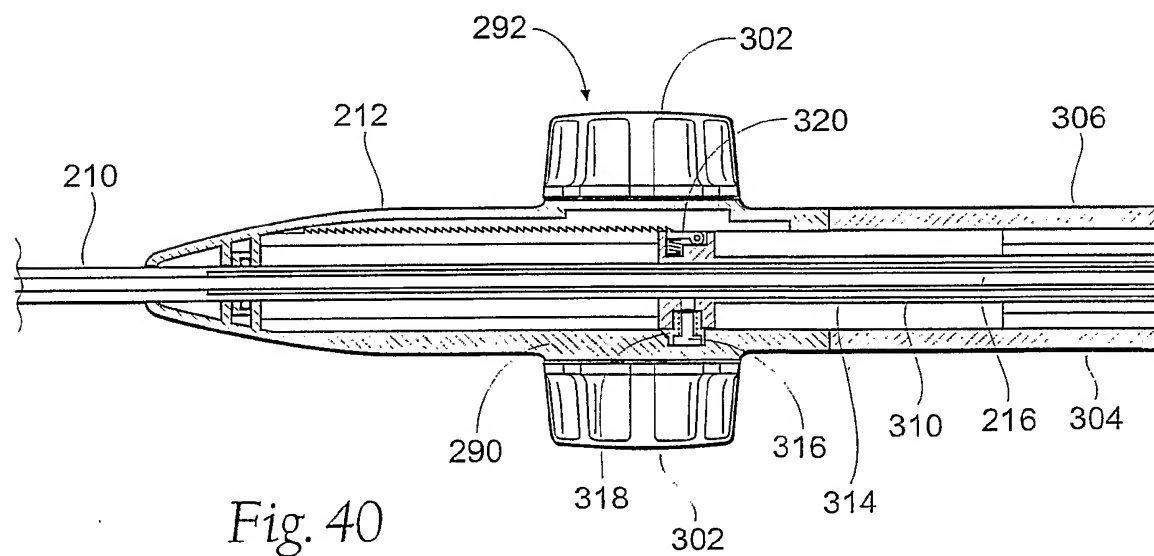
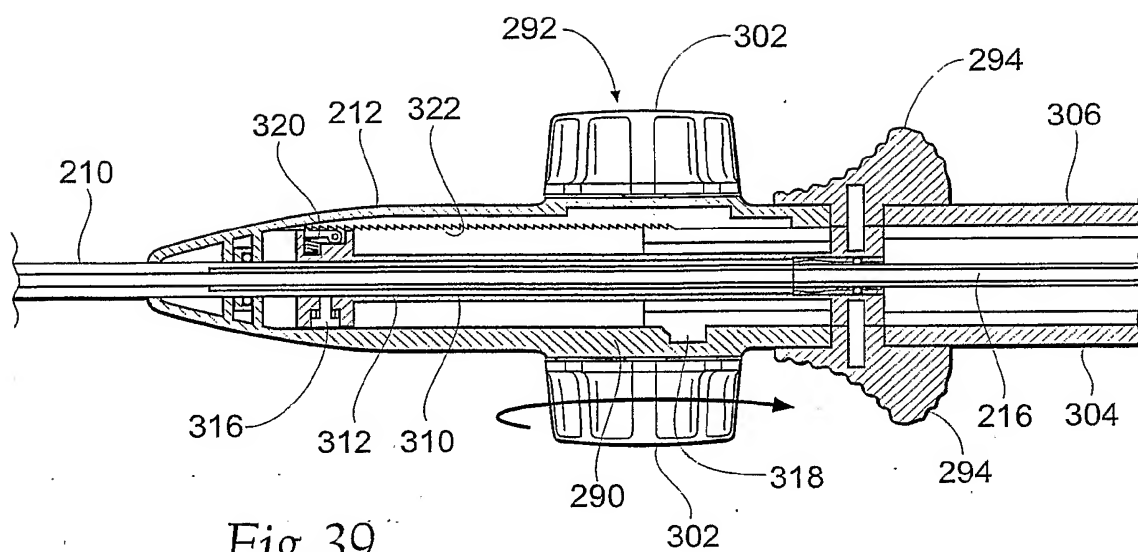
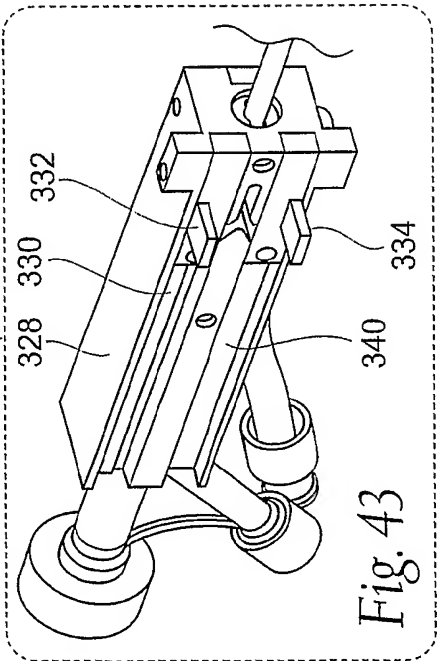
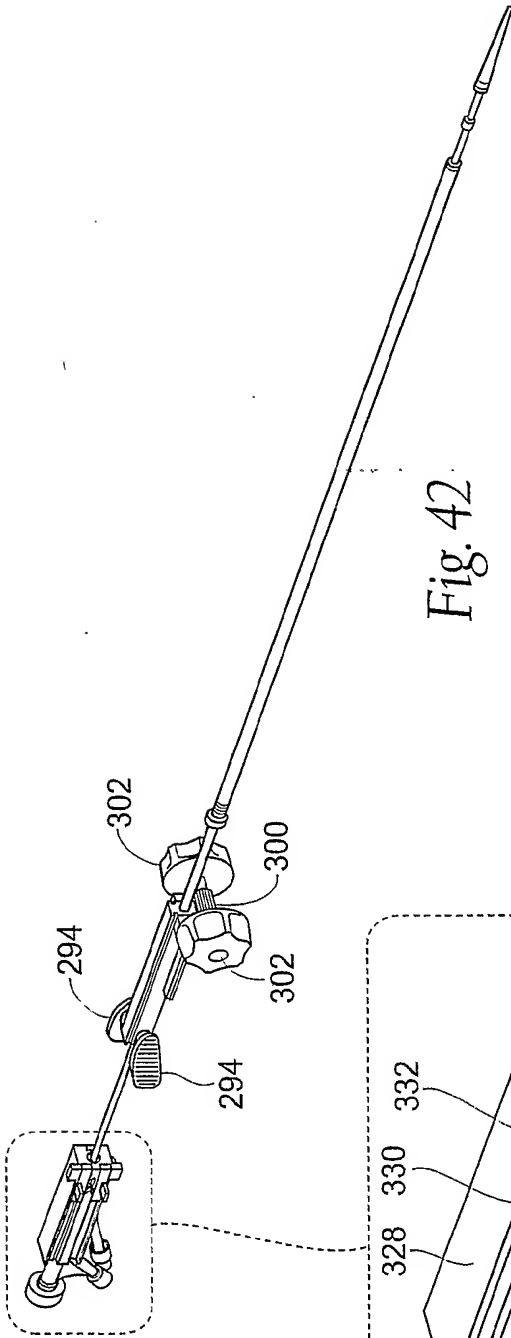
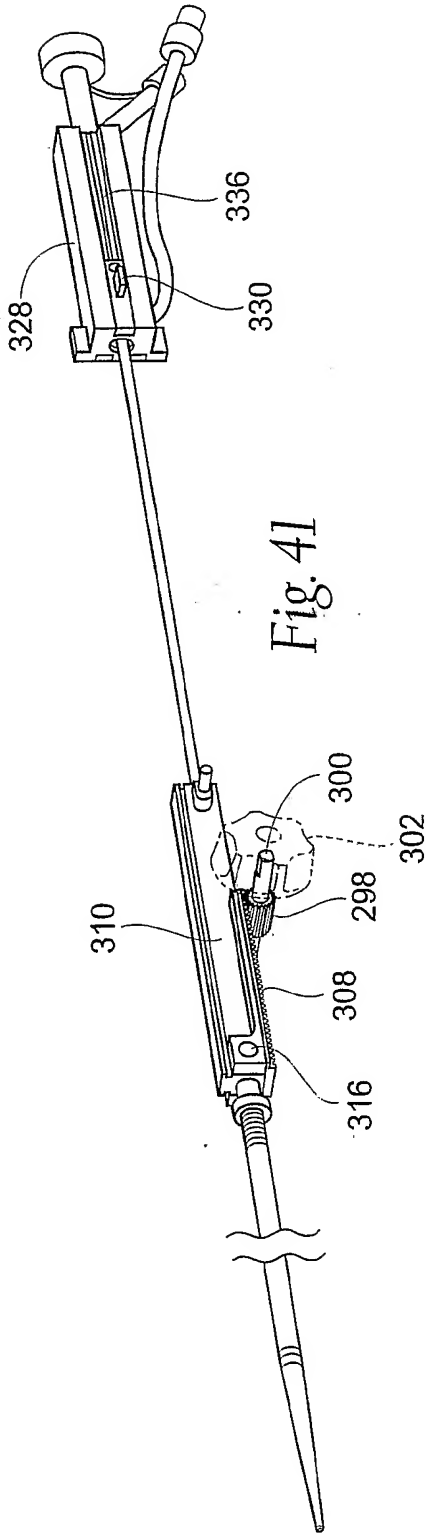


Fig. 38





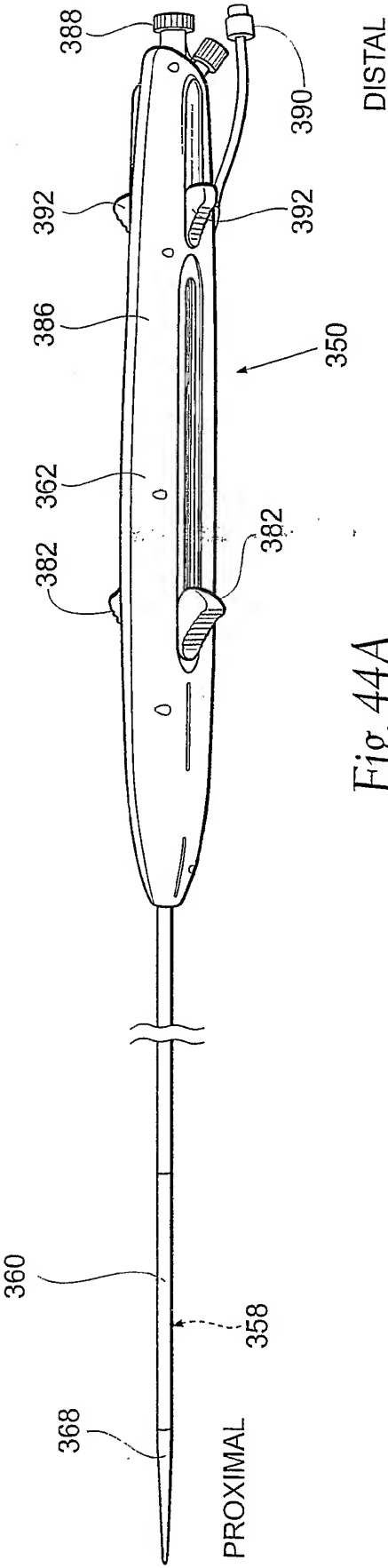


Fig. 44A

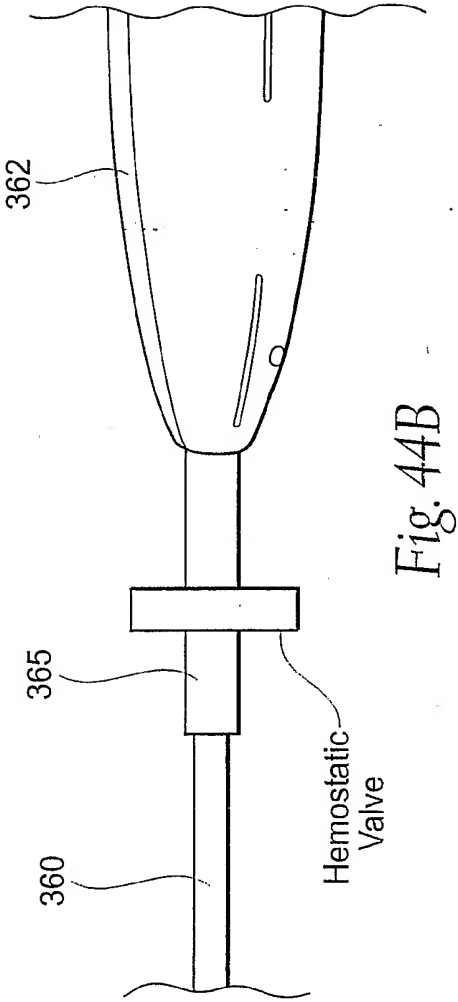


Fig. 44B

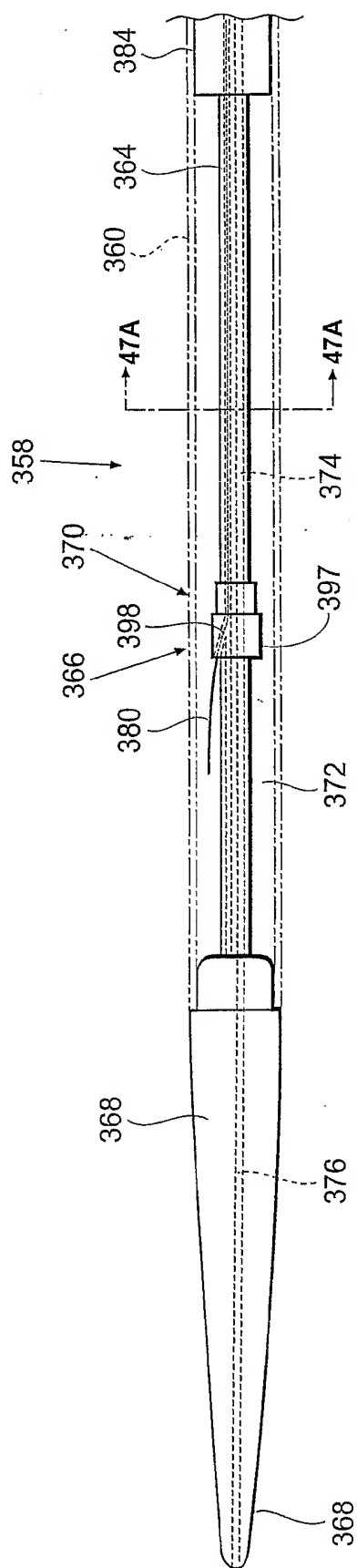


Fig. 45A

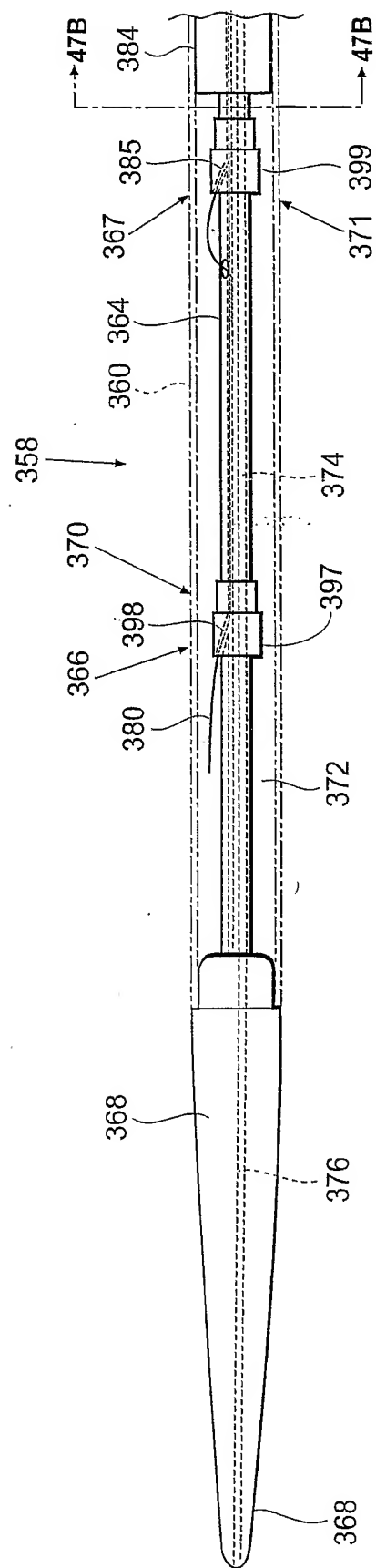


Fig. 45B

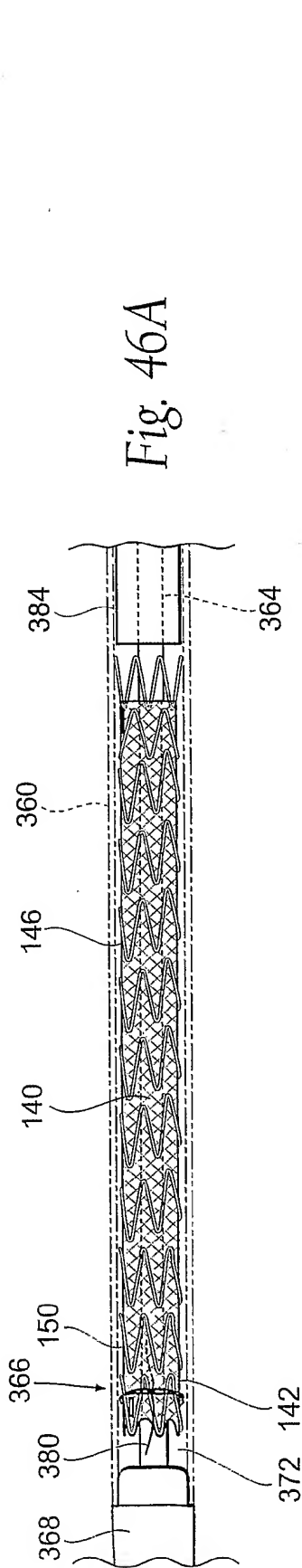


Fig. 46A

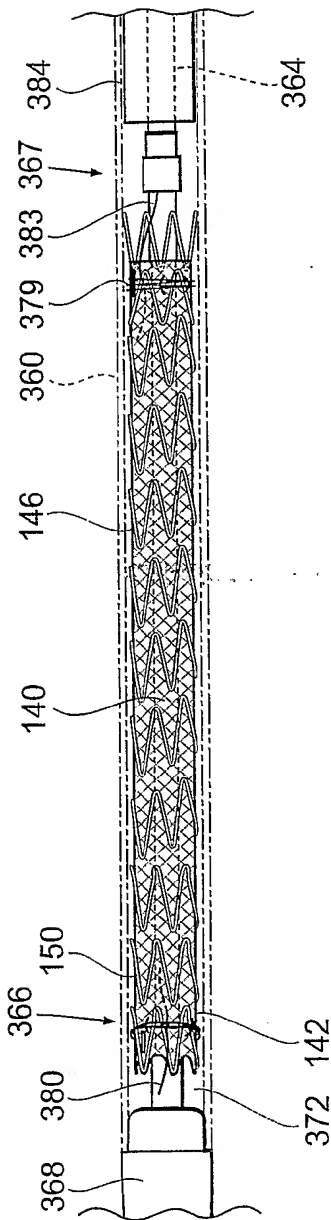


Fig. 46B

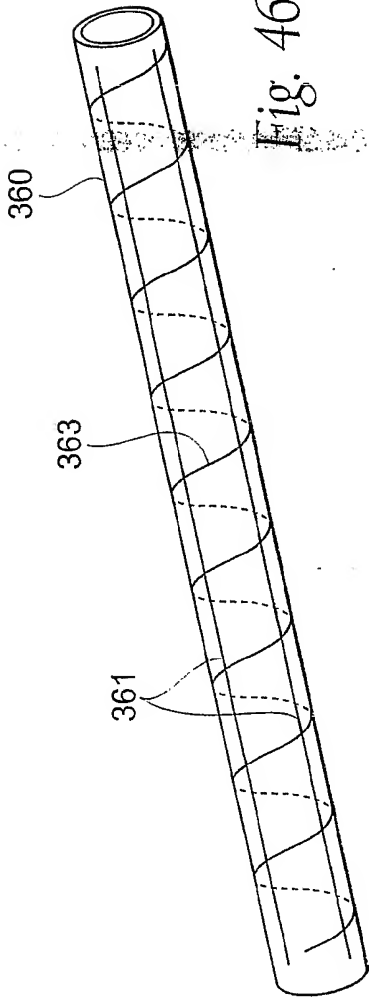


Fig. 46C

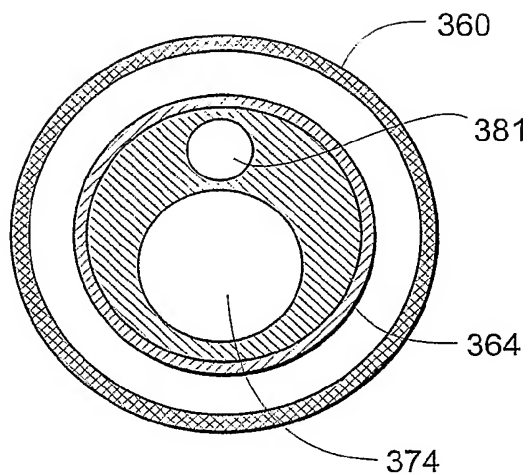


Fig. 47A

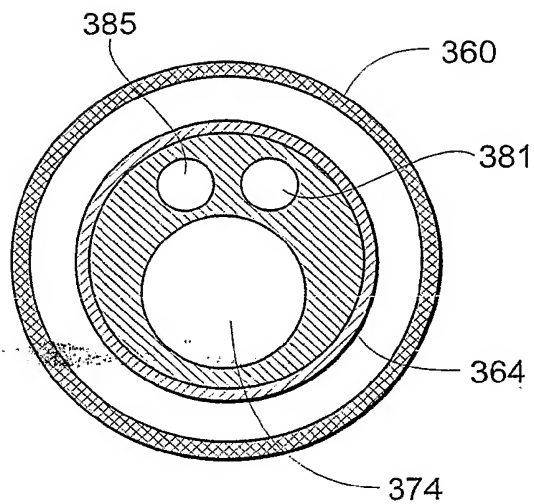


Fig. 47B

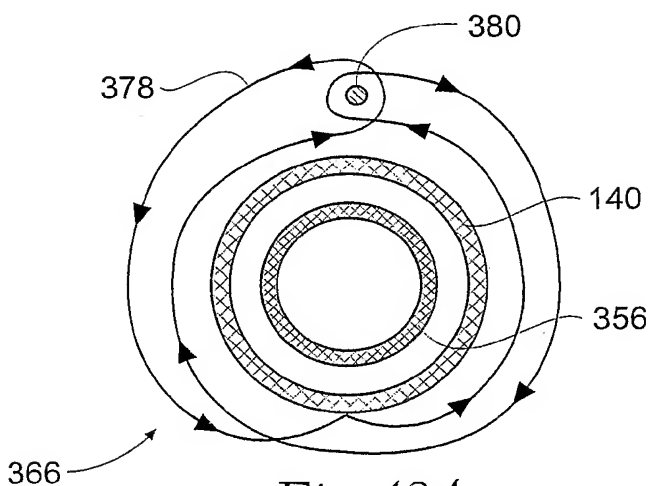


Fig. 48A

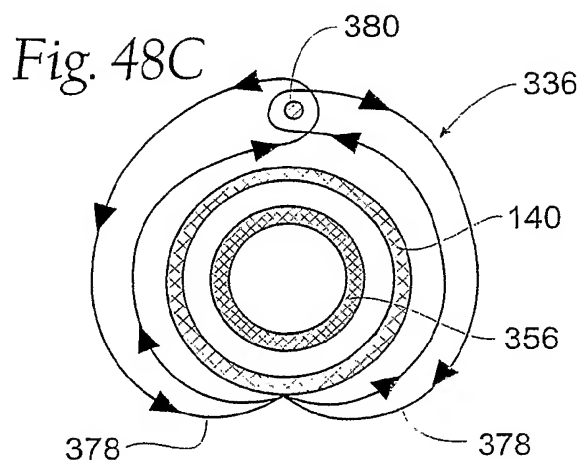


Fig. 48C

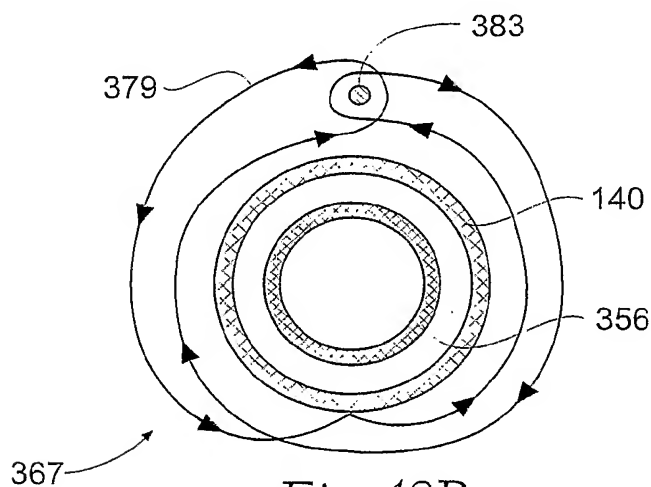


Fig. 48B

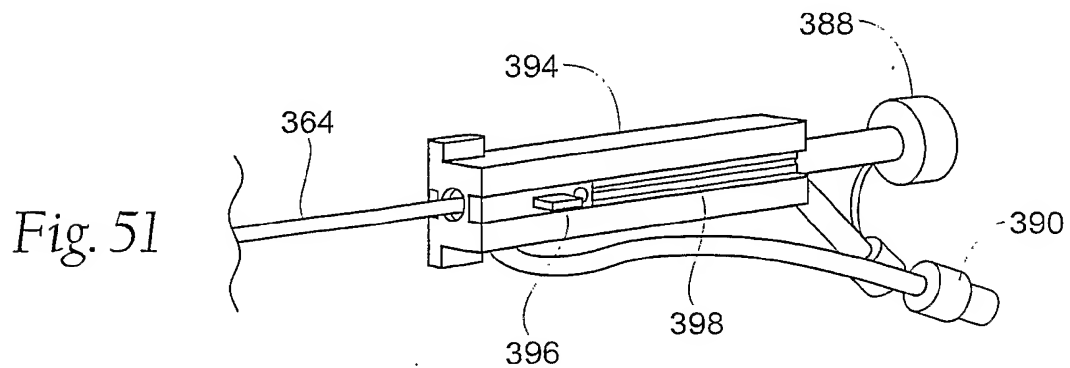
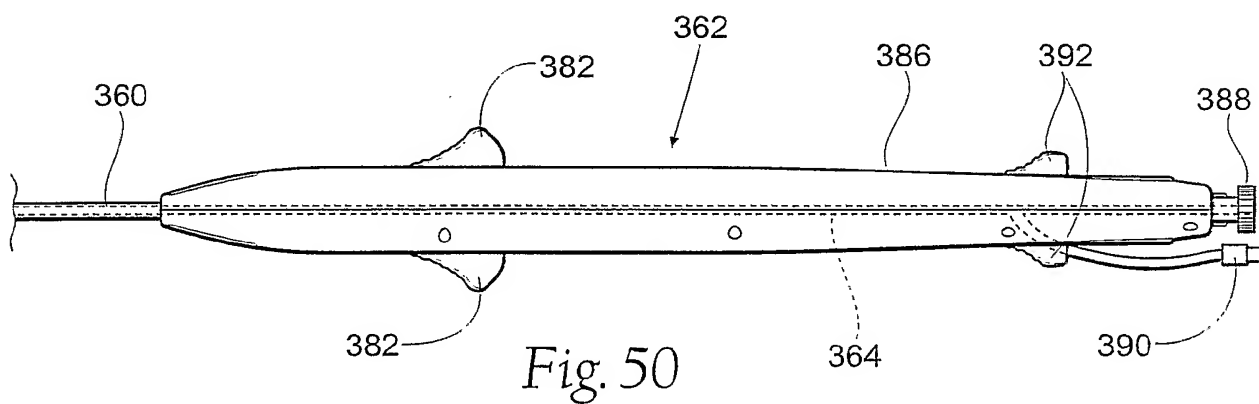
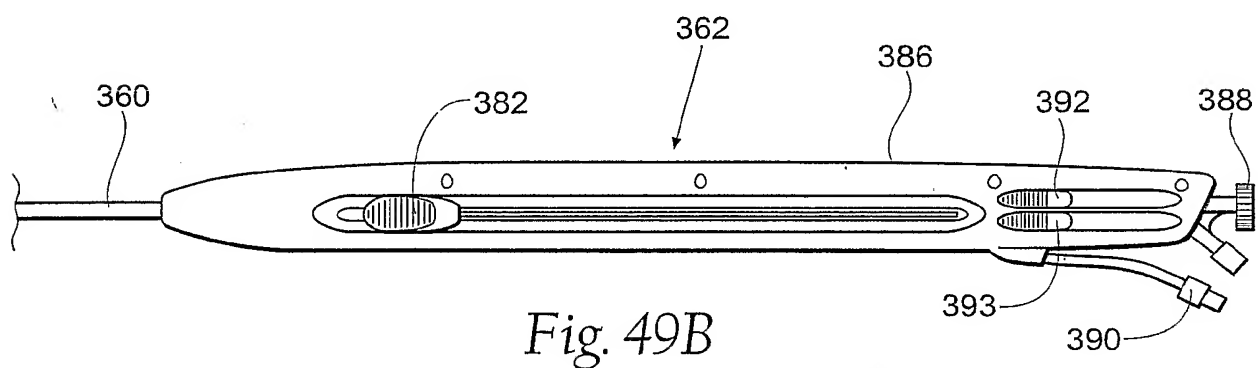
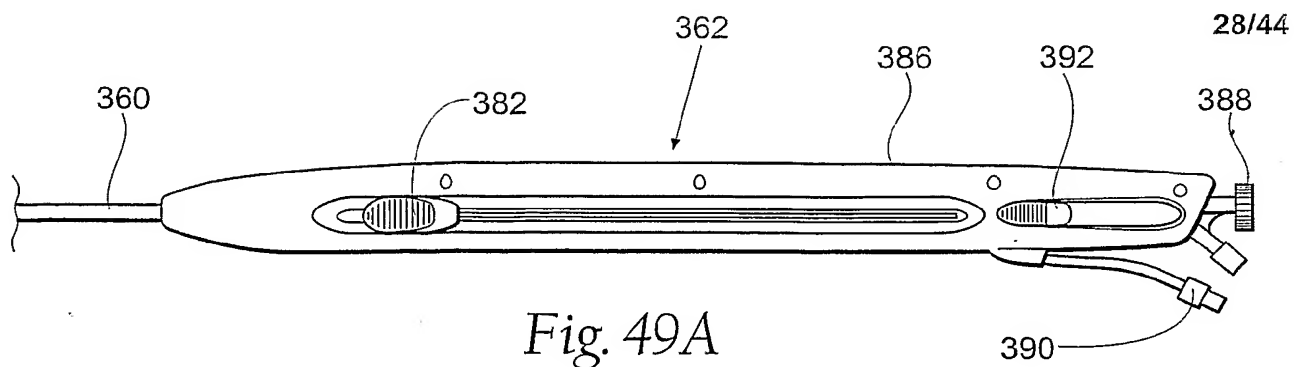


Fig. 52

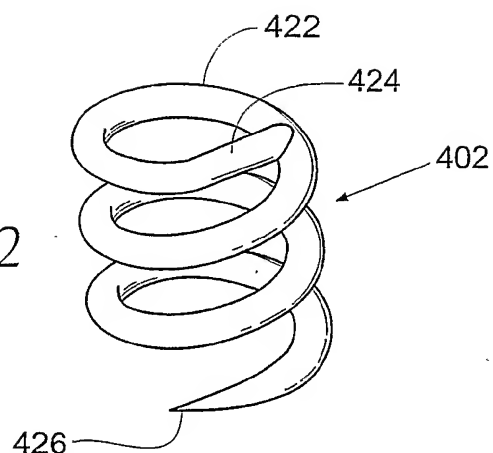


Fig. 53

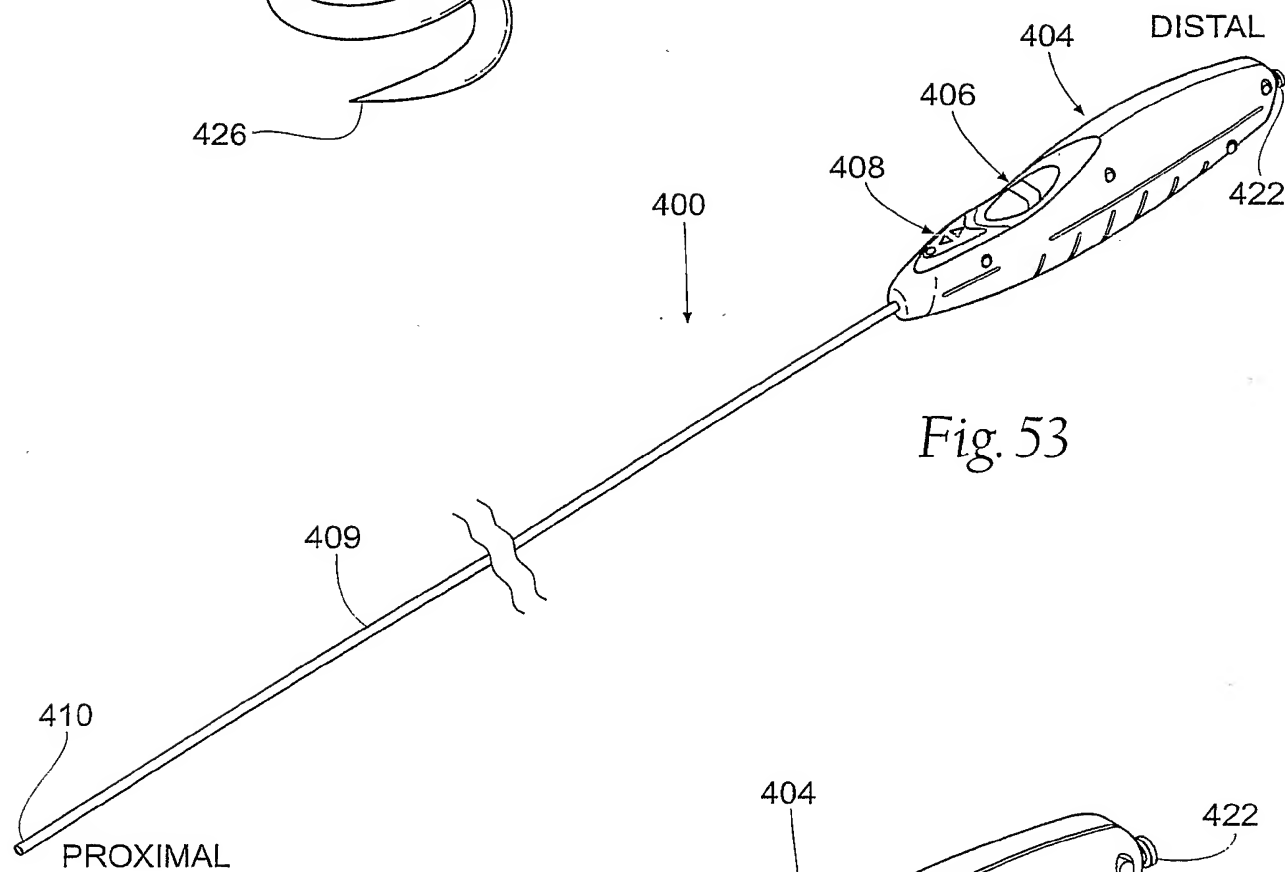
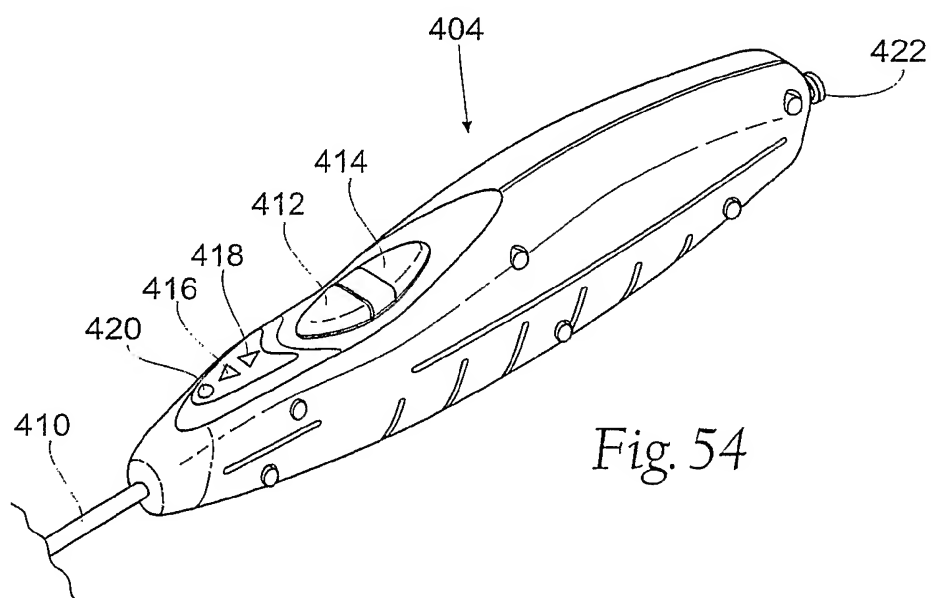
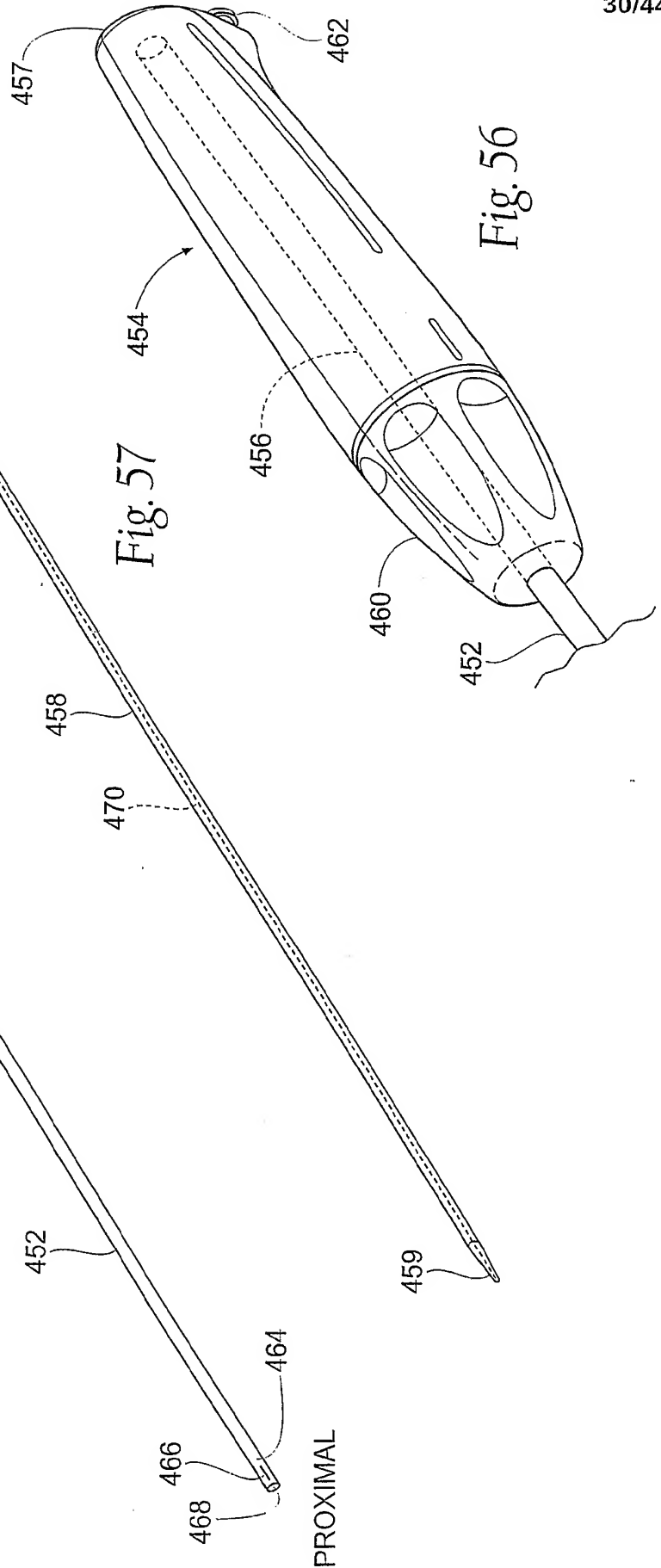
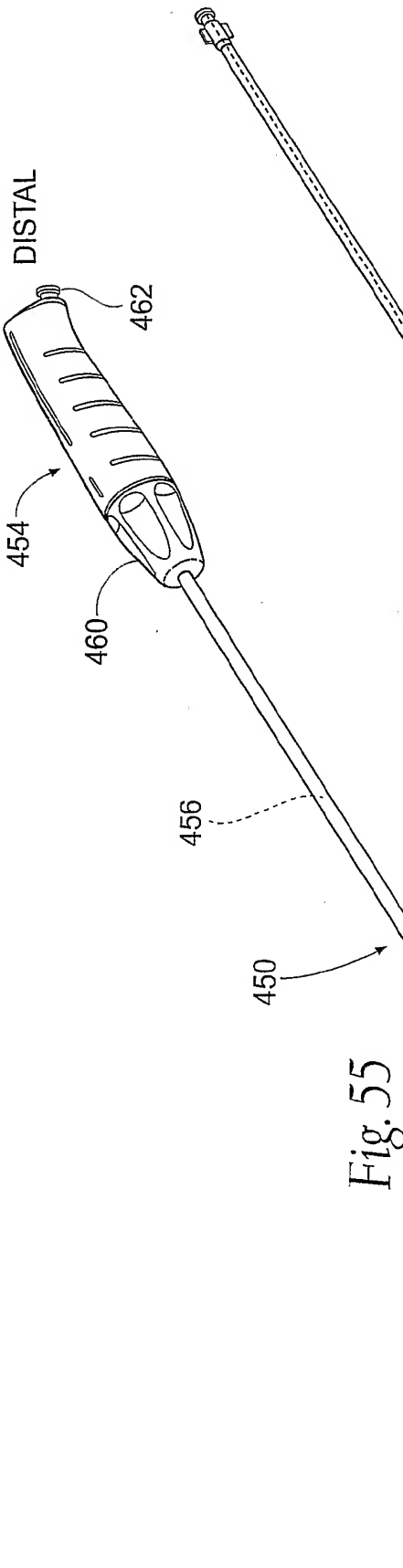
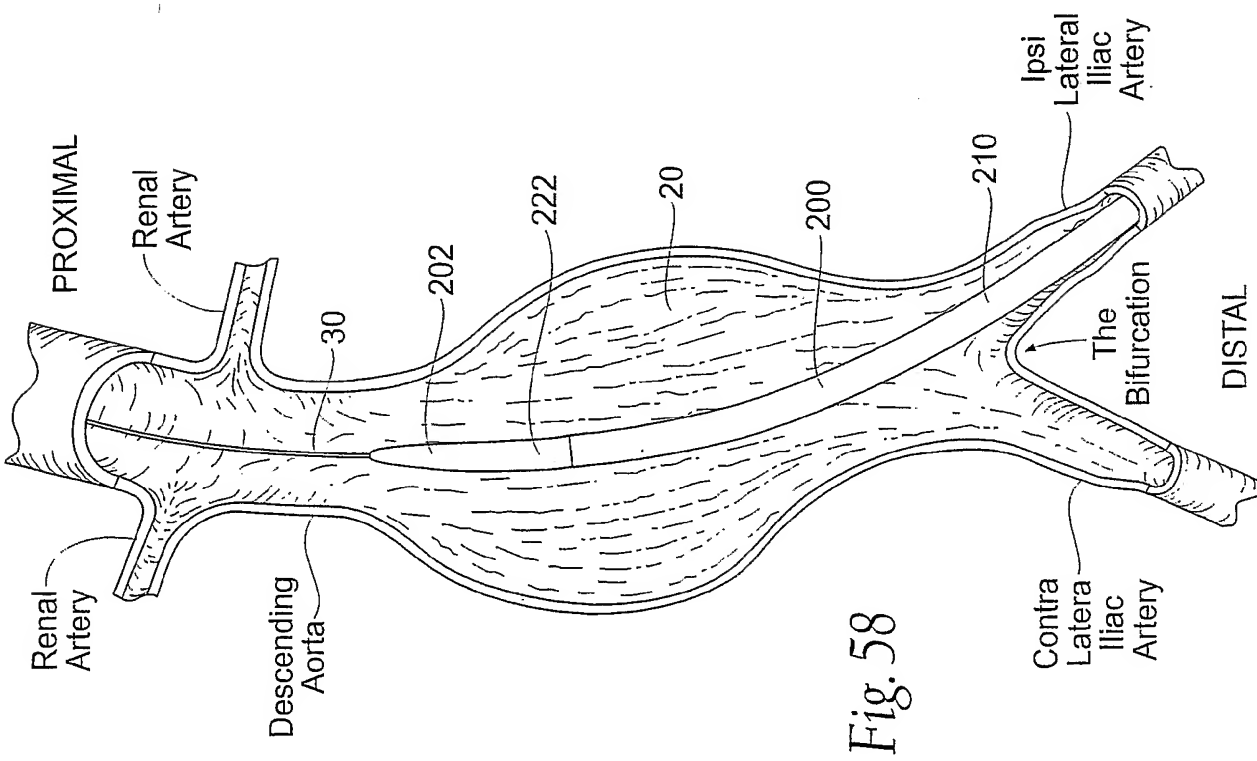
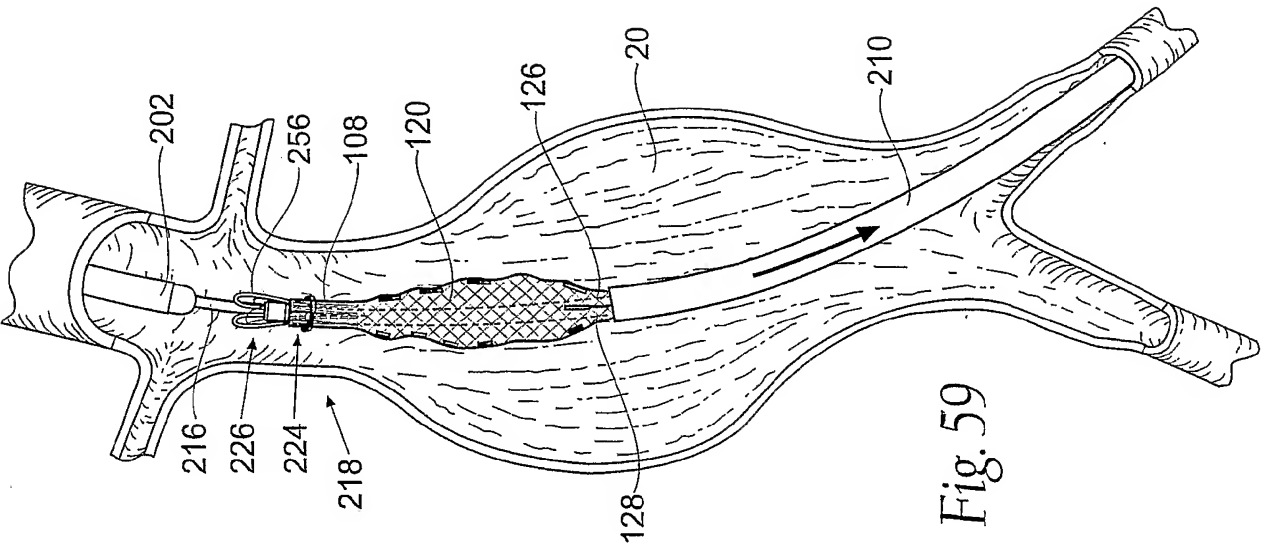


Fig. 54







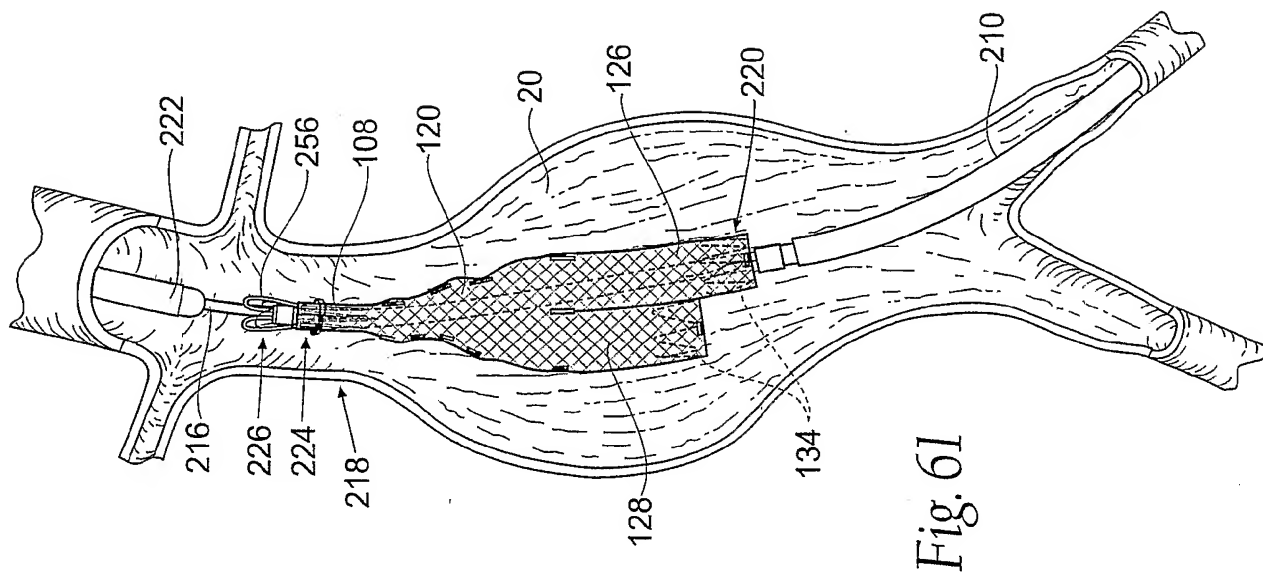


Fig. 60

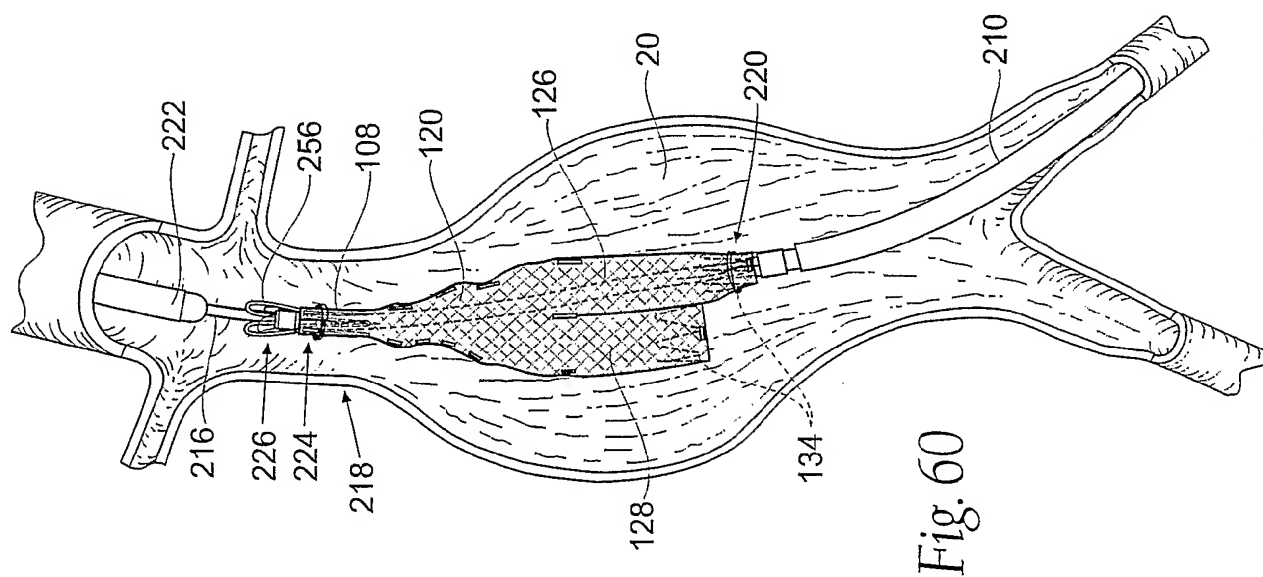
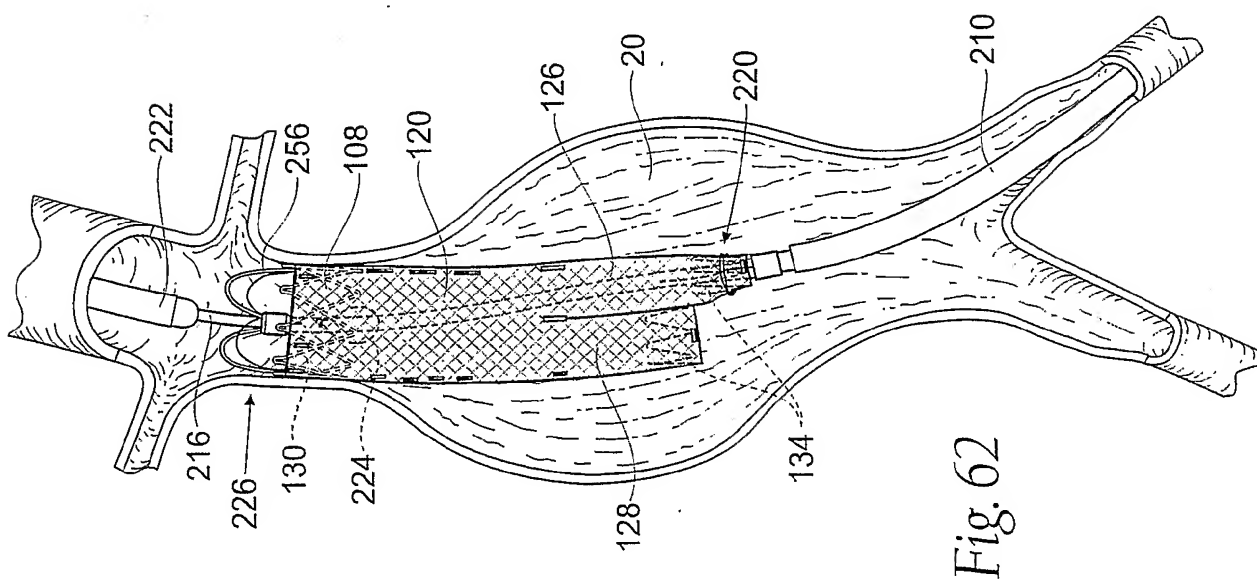
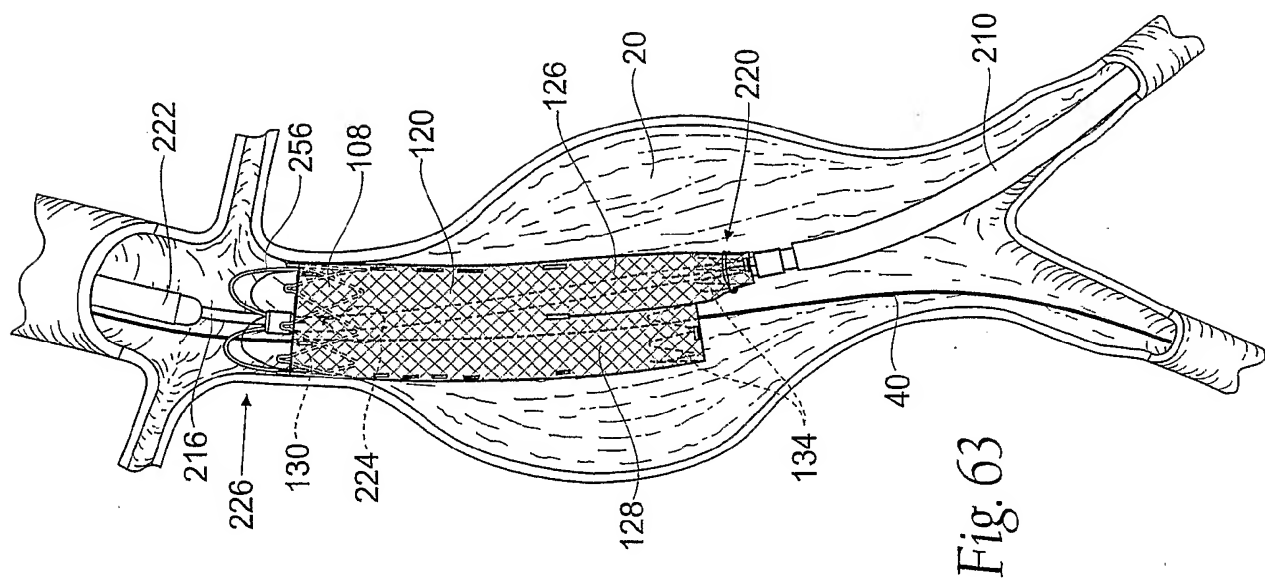
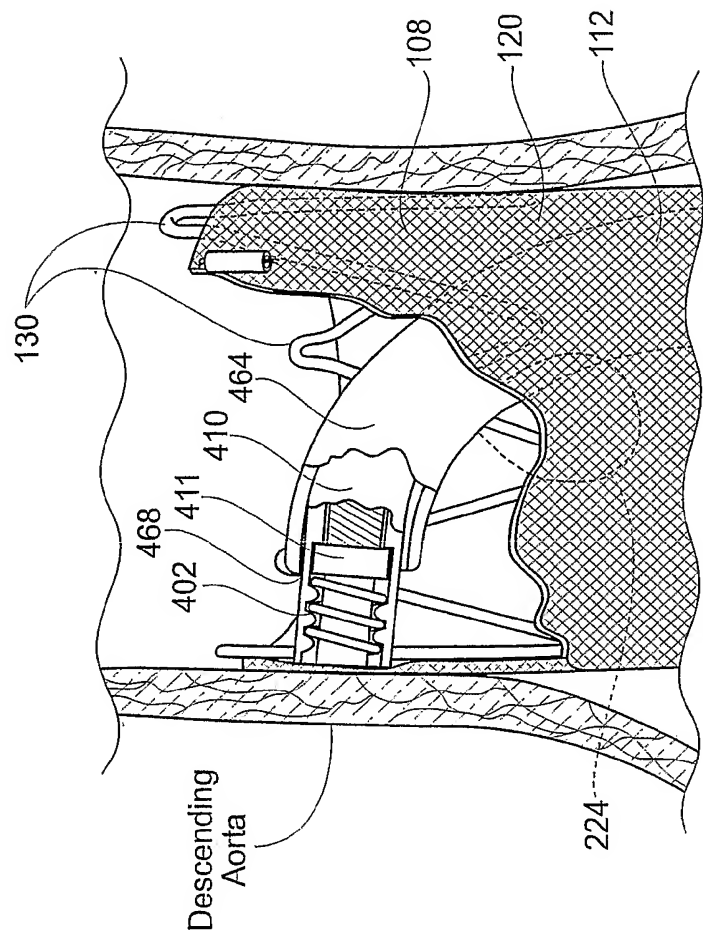
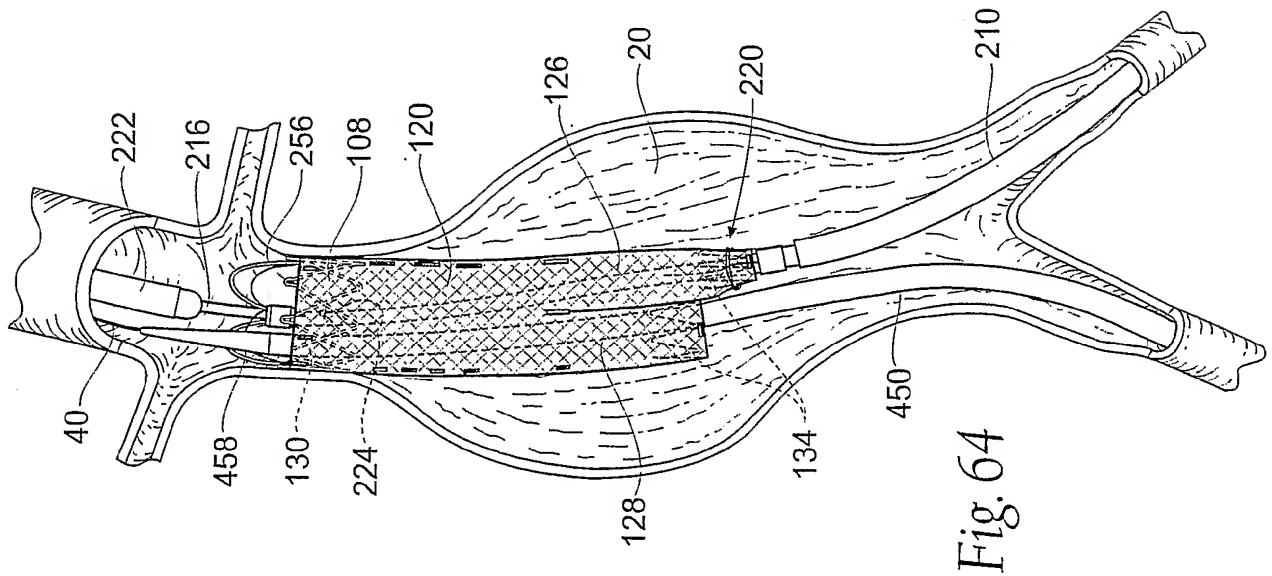
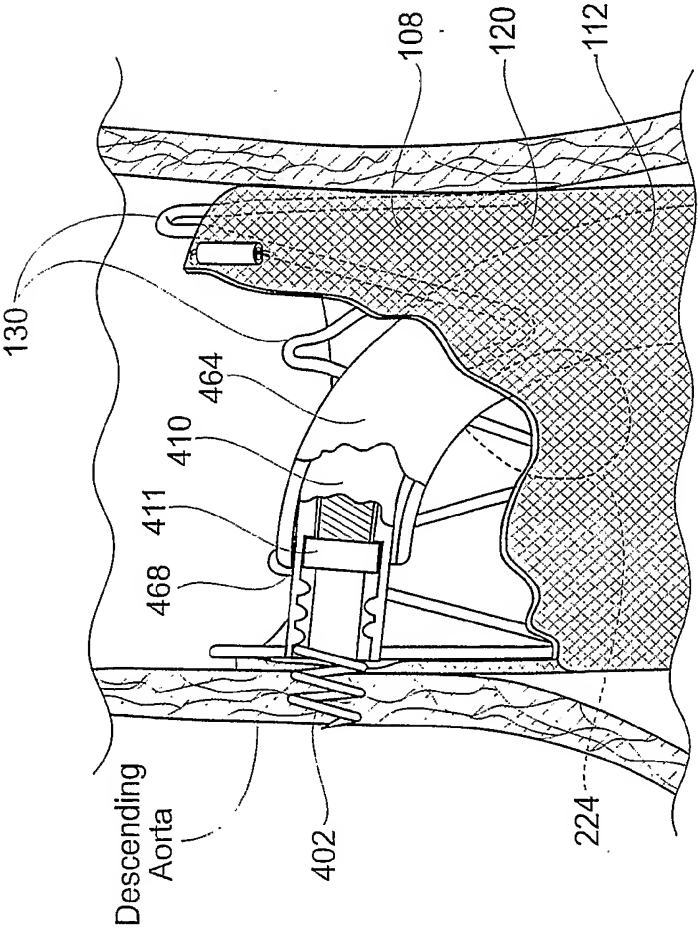
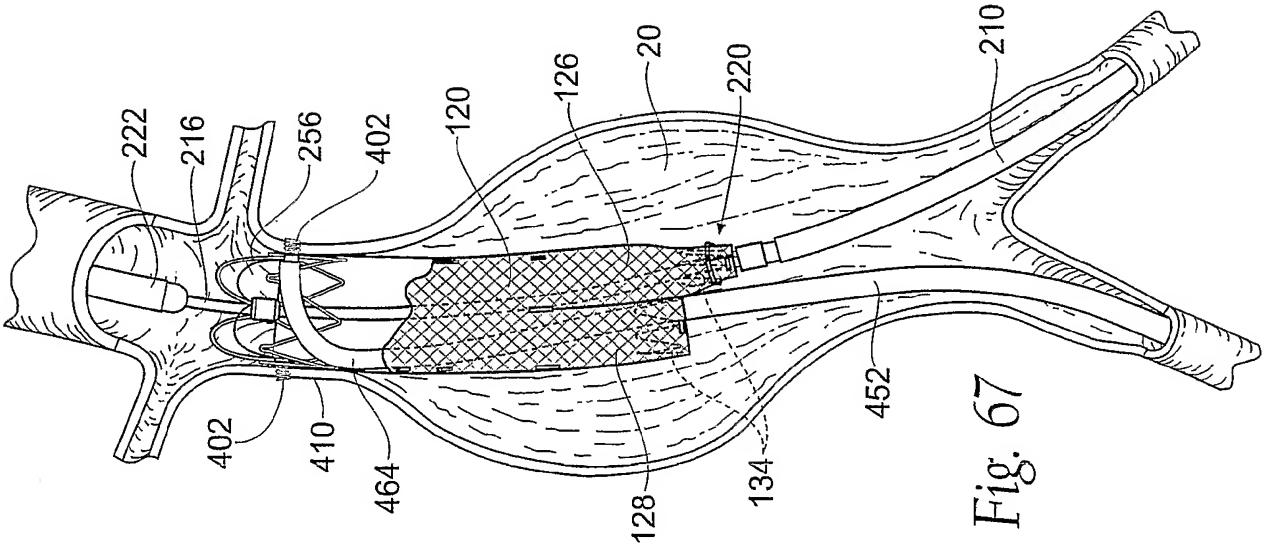
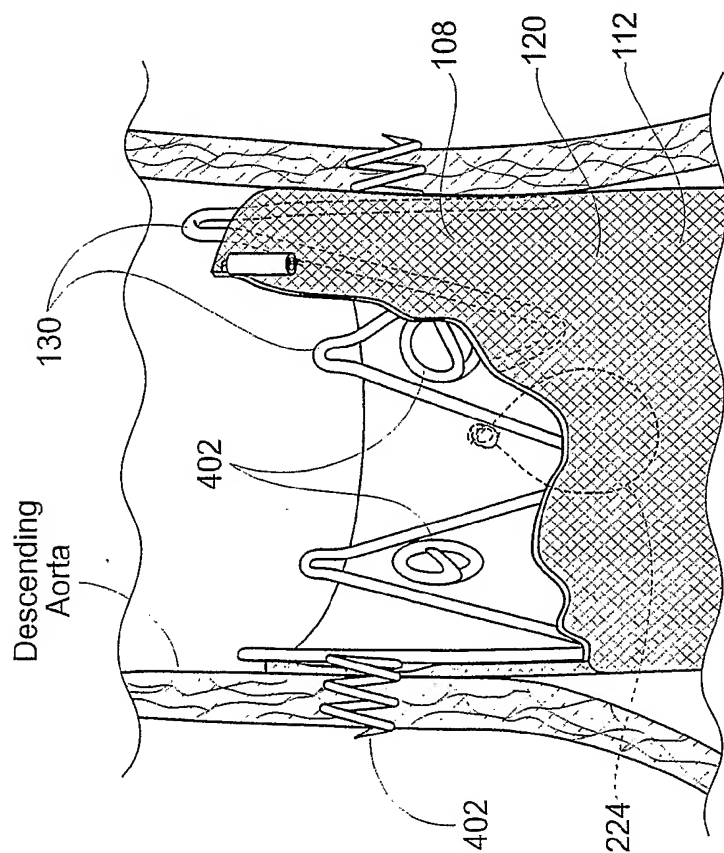
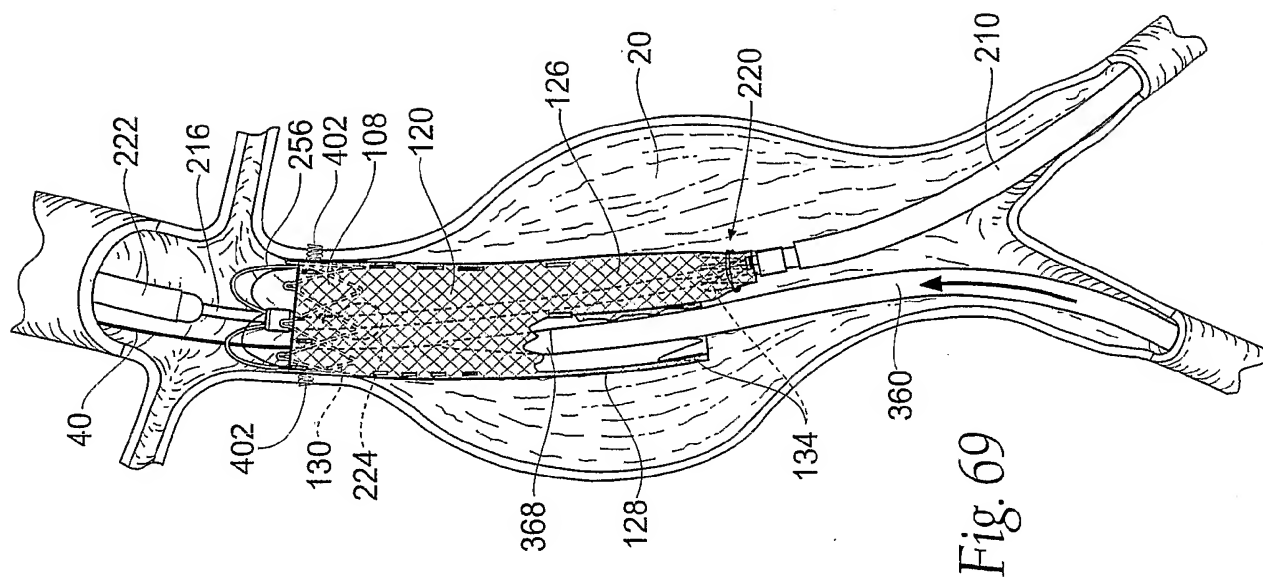


Fig. 61









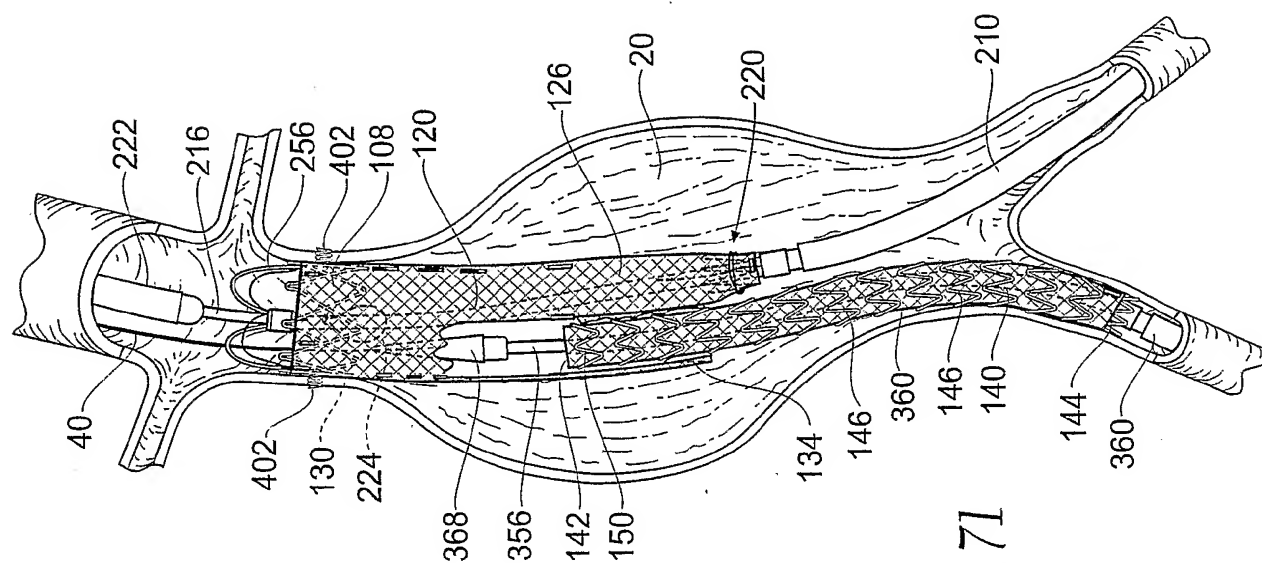


Fig. 71

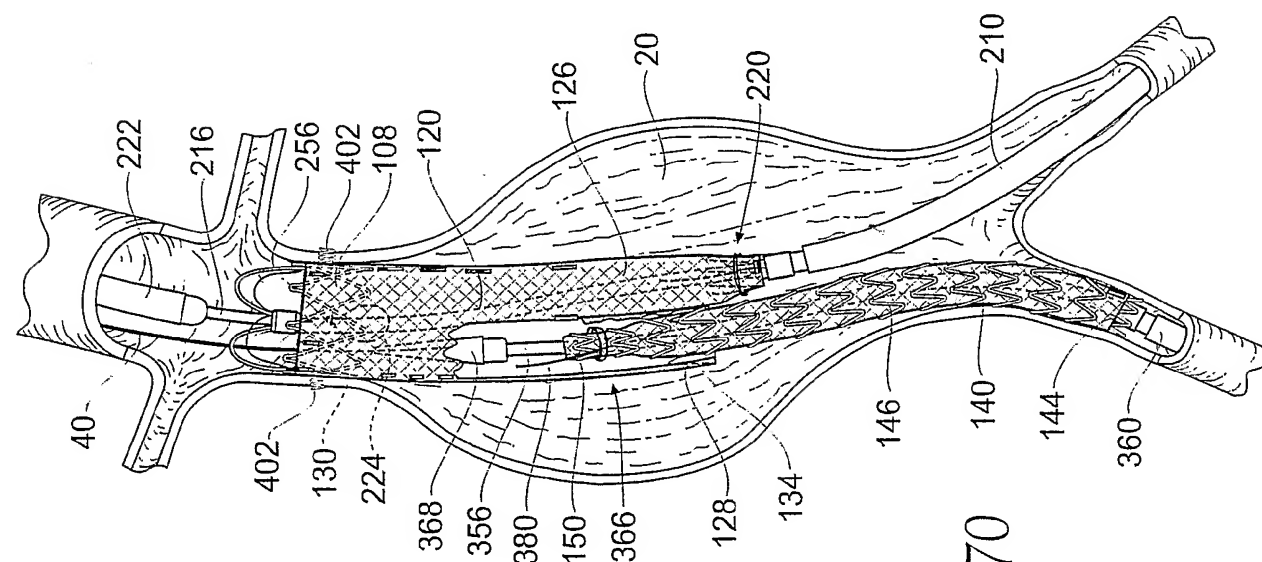


Fig. 70

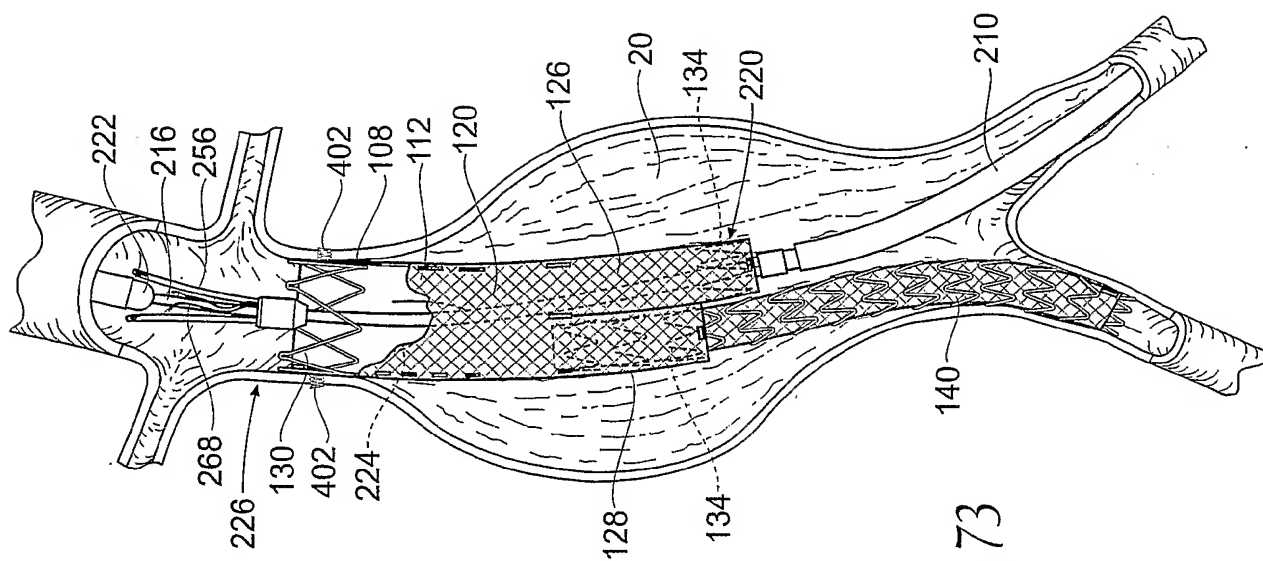


Fig. 73

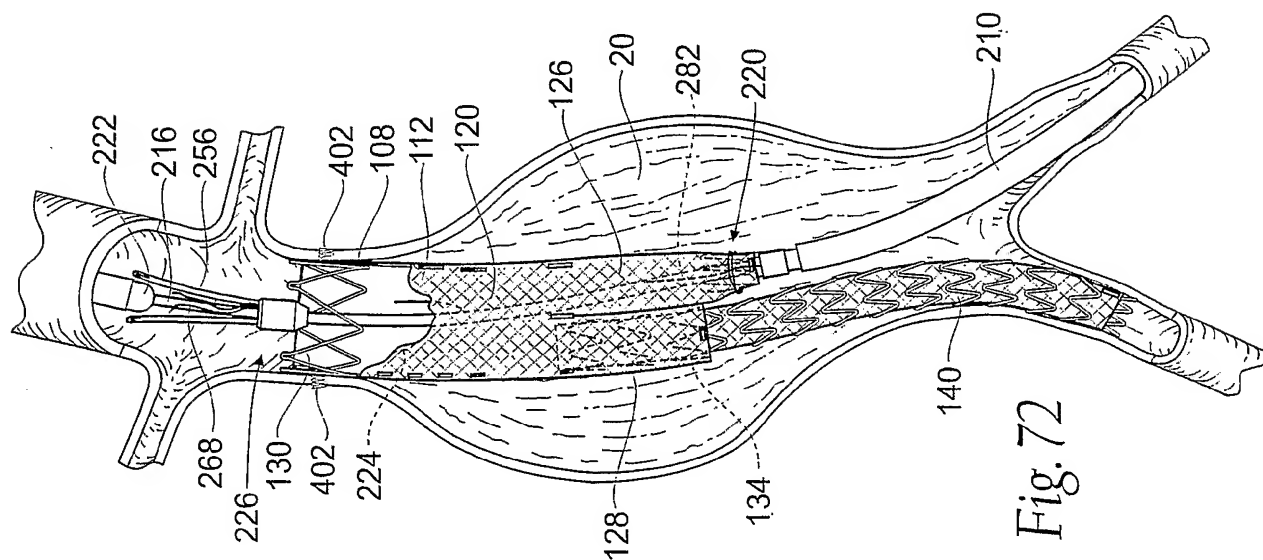


Fig. 72

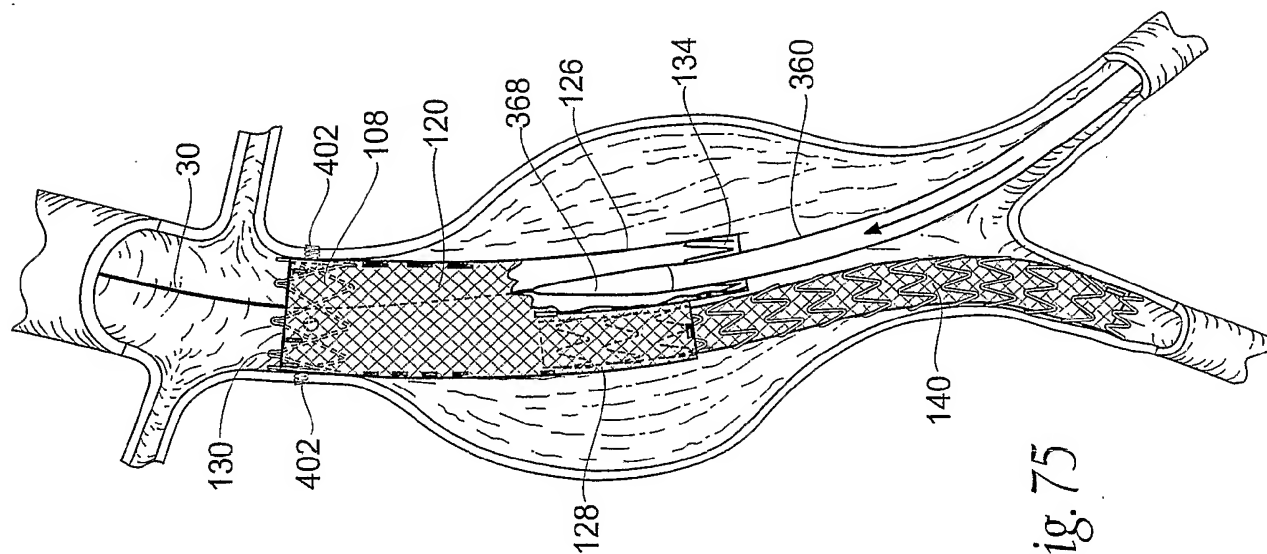


Fig. 75

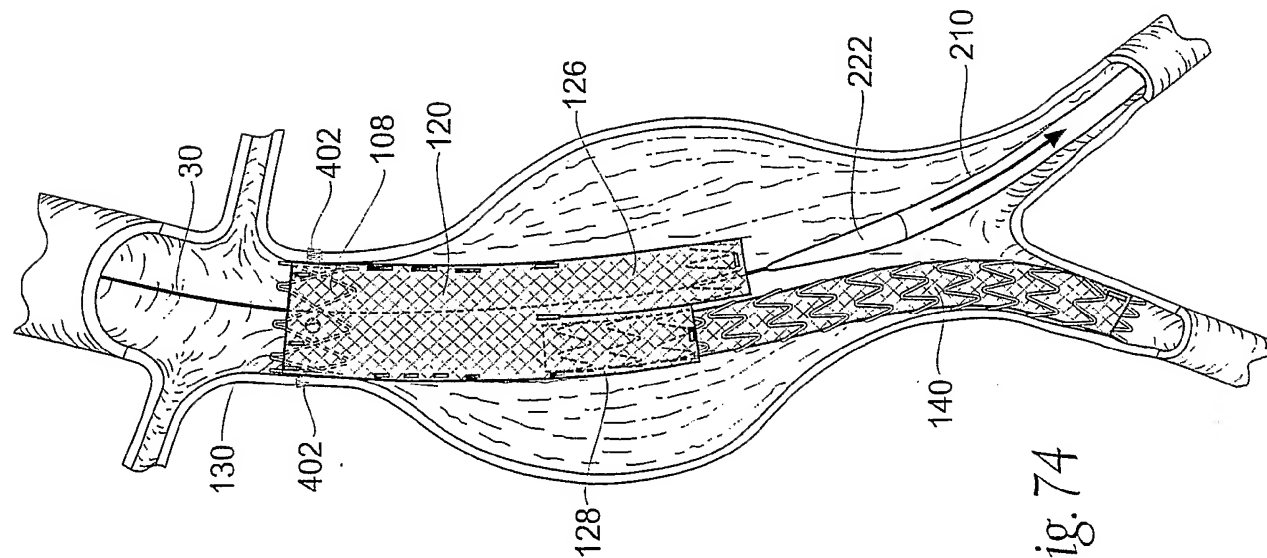


Fig. 74

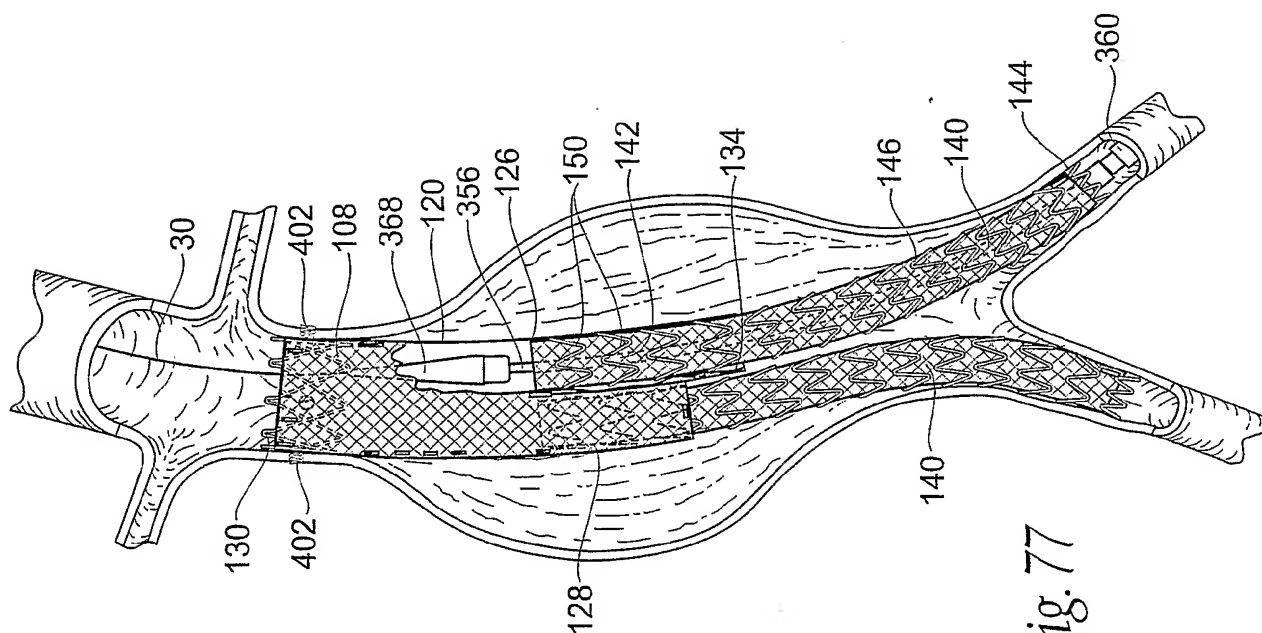


Fig. 77

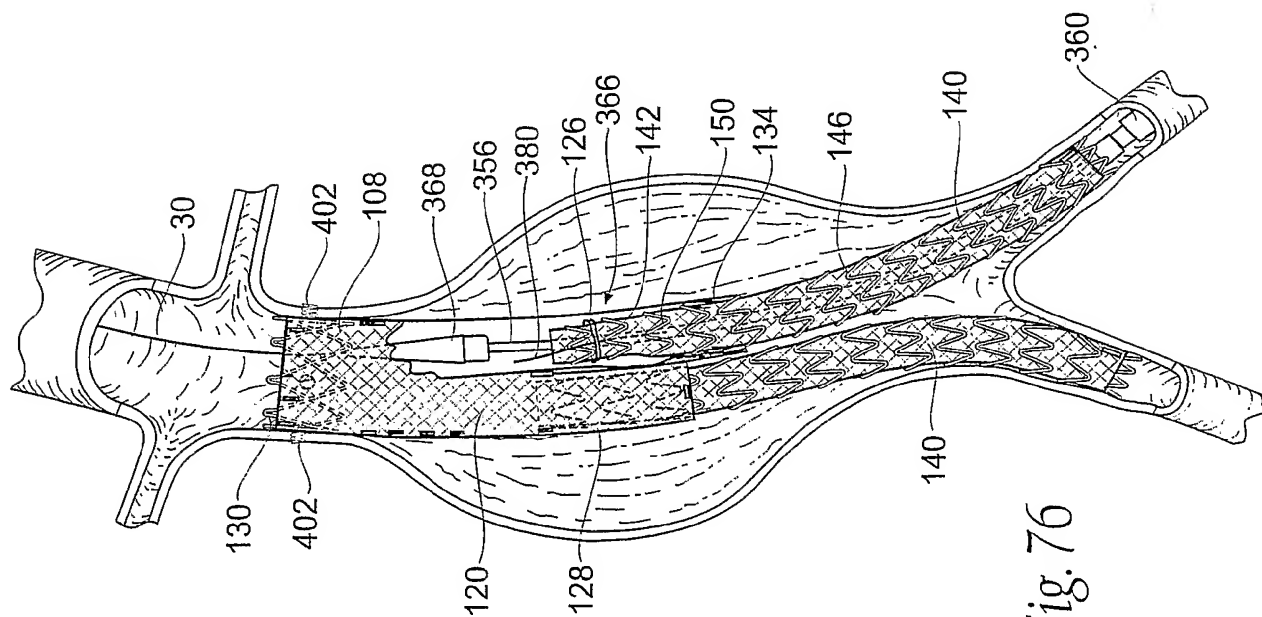
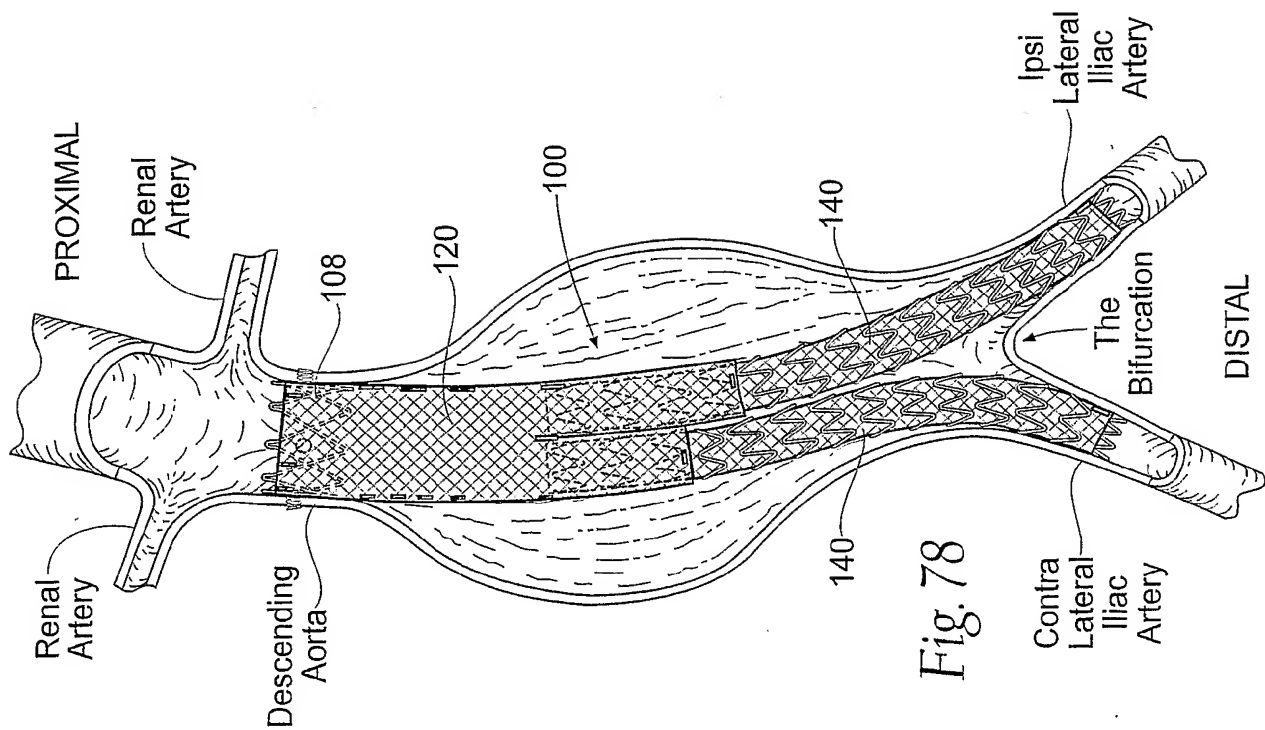


Fig. 76



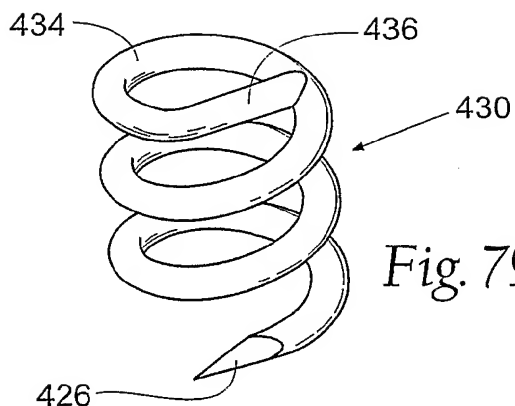


Fig. 79A

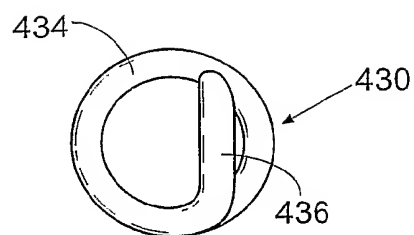


Fig. 79B

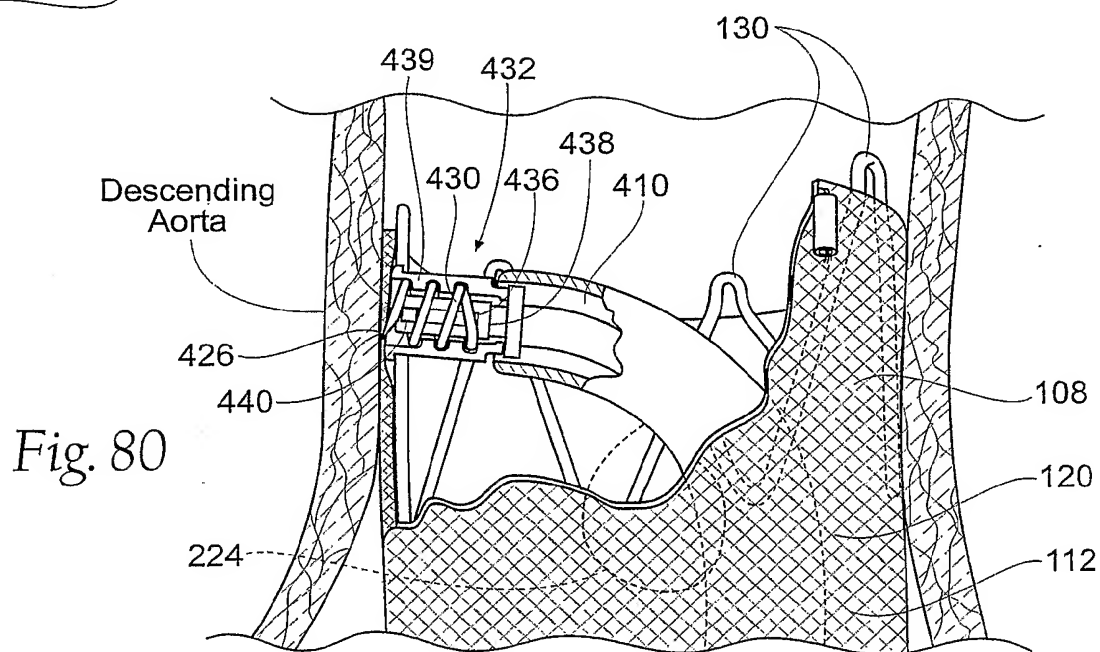


Fig. 80

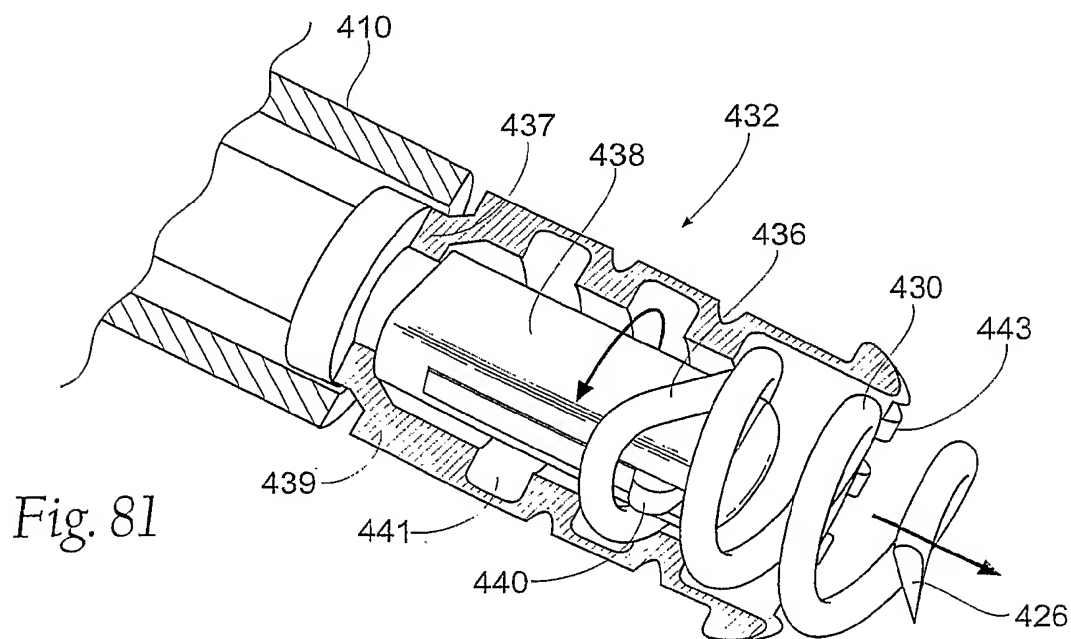


Fig. 81

Fig. 82A

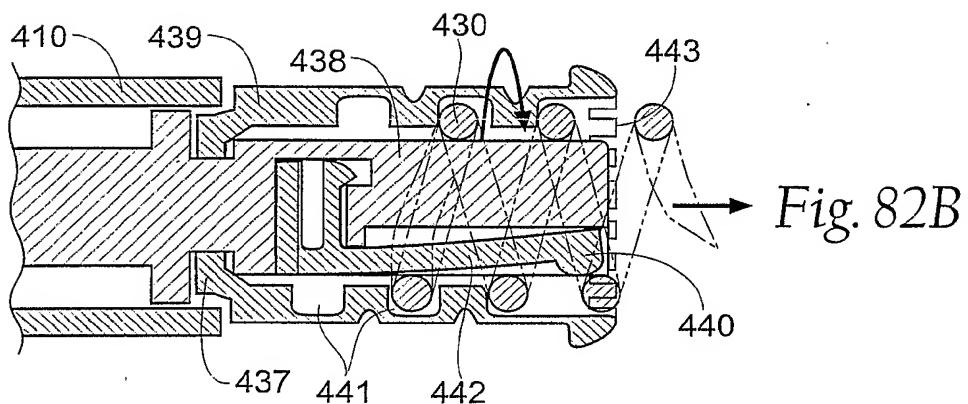
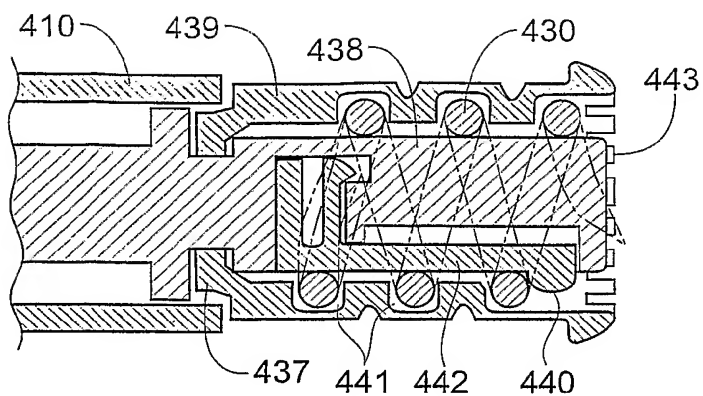


Fig. 82C

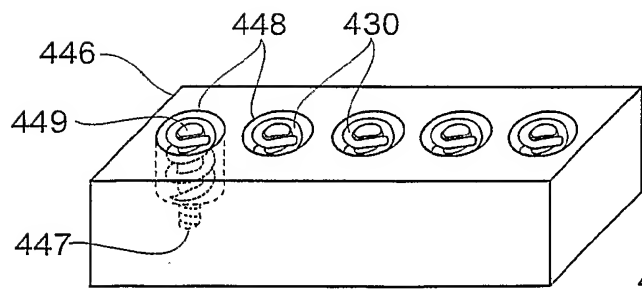
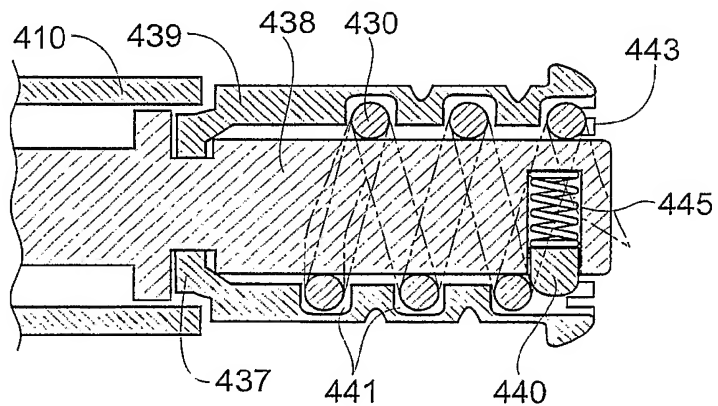


Fig. 83

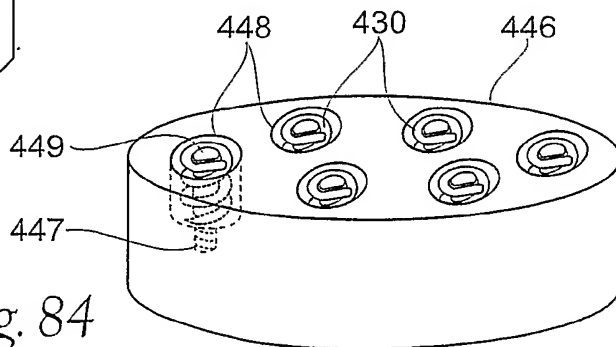
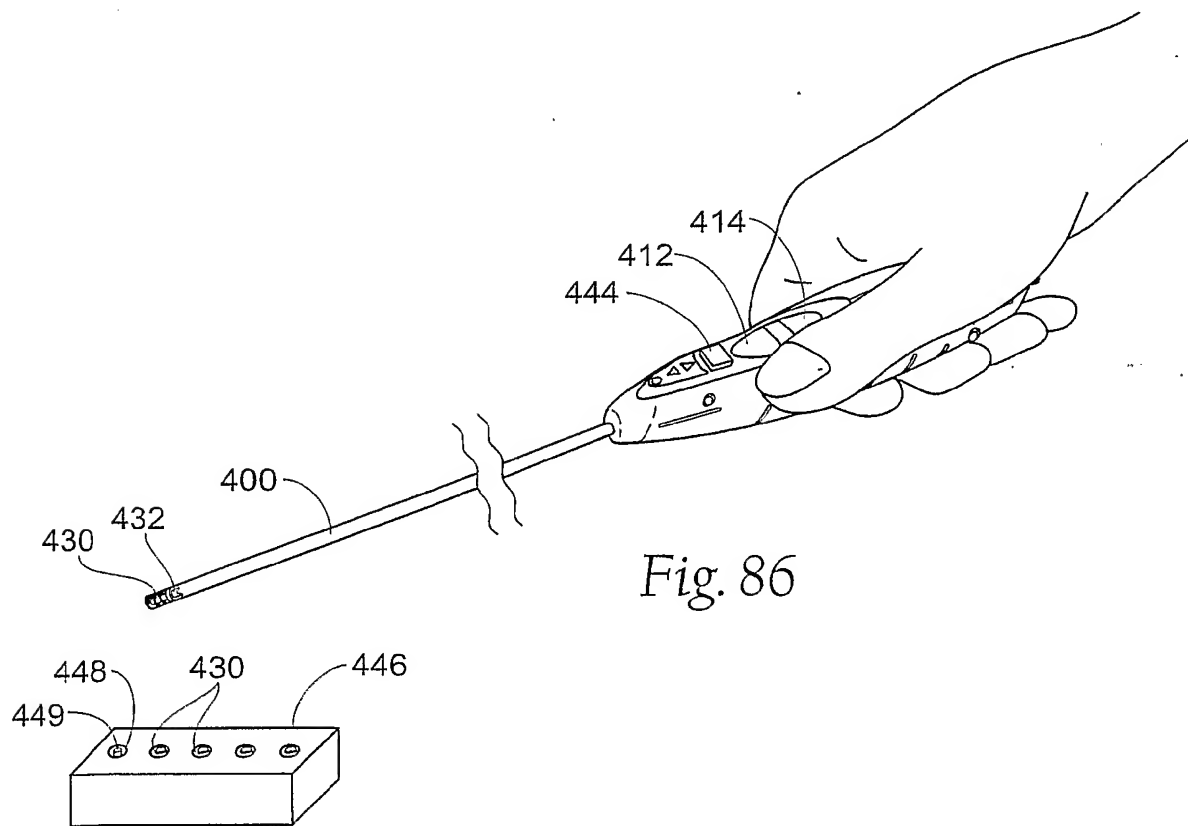
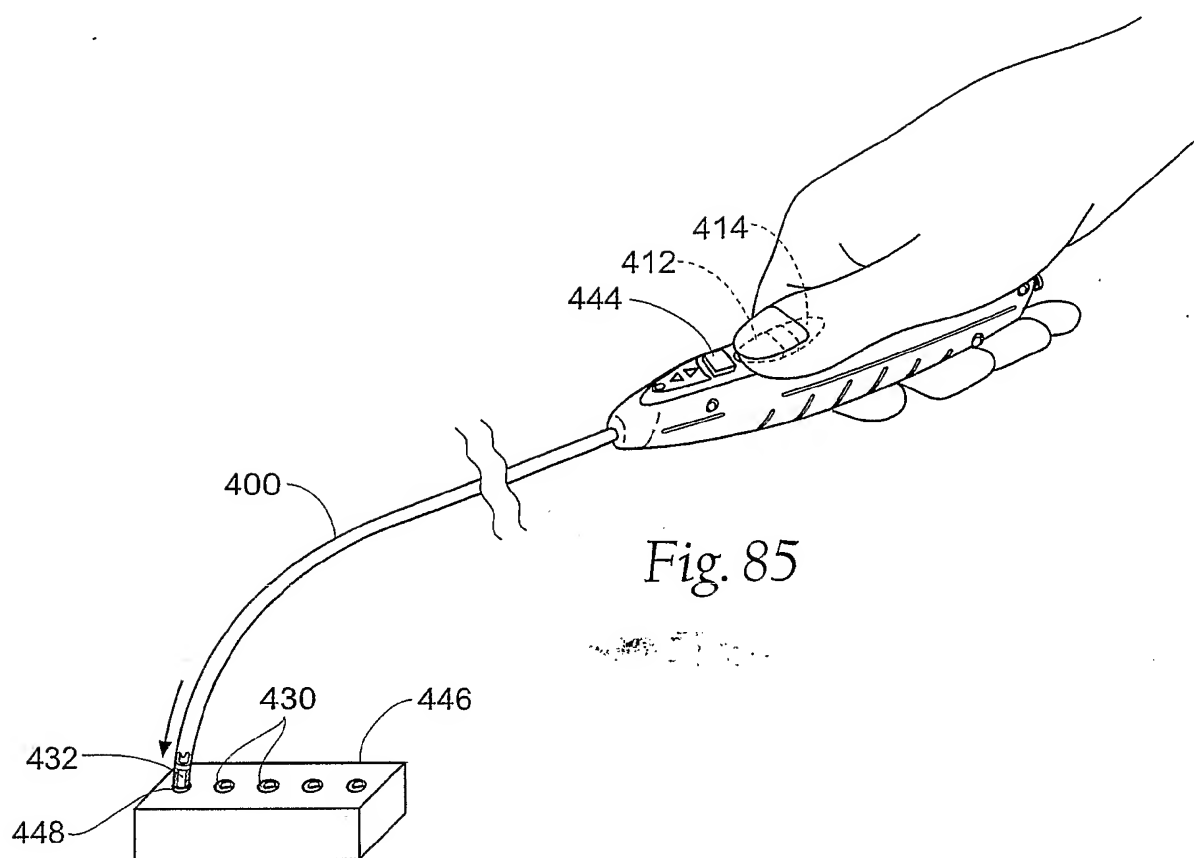


Fig. 84



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(54) Title: DEVICES, SYSTEMS, AND METHODS FOR PROSTHESIS DELIVERY AND IMPLANTATION, INCLUDING
THE USE OF A FASTENER TOOL

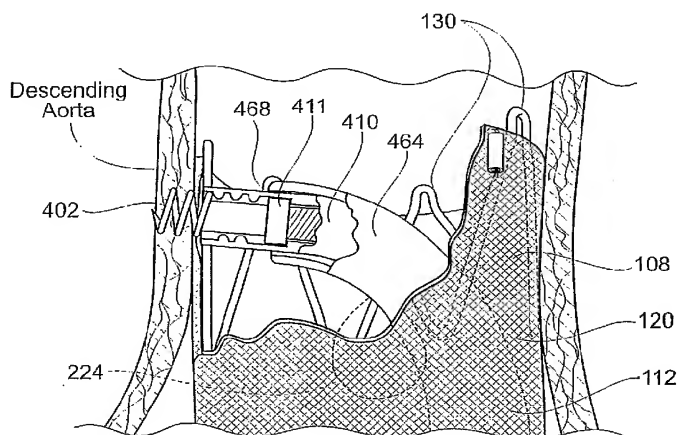


Fig. 66

(57) Abstract: Devices, systems, and methods for implanting radially expandable prostheses in the body lumens rely on tacking or anchoring the prostheses with separately introduced fasteners. The prostheses may be self- expanding or balloon expandable, and may include a single lumen or more than one lumen. After initial placement, a fastener applier system is introduced within the expanded prostheses to deploy a plurality of fasteners to at least one prosthesis end. The fasteners are usually helical fasteners which are releasably restrained on the fastener driver, and are delivered by rotation of the fastener driver. The fasteners may be applied singly, typically in circumferentially spaced- apart patterns about the interior of at least one end of the prosthesis. A lumen extension or lumens may be coupled to the prosthesis to extend the reach of the prosthesis within the implantation site. Fasteners may also be applied to the lumen extensions .

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International application No.

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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/139-143, 151, 213; 227/175.1-182.1, 901

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2004/0093057 A1 (BOLDUC et al.) 13 May 2004 (13.05.2004), paragraph [0088]-[0116], figures 7-25	1-3, 5-22
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Y		4
Y	US 2005/0187613 A1 (BOLDUC et al.) 25 August 2005 (25.08.2005), paragraph [0129]	4

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☐ See patent family annex.

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